UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 28, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 10 A.M. SESSION

(Pages 2160 - 2296)

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Proceedings Reported by Stenographic Court Reporter
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I N D E X

EXAMINATION

EXHIBITS

10:01:31

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:30:22

THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: We are going to get you later this morning the final jury instructions for your review and

08:30:52 comment. We probably ought to just get any final comments on those sometime during the lunch hour.

We think we'll have them to you before then, but I'm not sure you'll have time to look at them until the lunch hour.

08:31:08

What matters do plaintiff want to raise this morning?

MR. MANKOFF: We have some questions about the admission of two documents still, the Grassi paper and the last four pages of the monthly report.

THE COURT: All right. What are the issues?

08:31:34

MR. MANKOFF: So there's still a dispute about whether the Grassi papers should come in and whether it's hearsay, so plaintiffs are objecting to the admission of that document. And we are still trying to argue that the last four pages of the monthly report come in under various exceptions

08:31:51 to the hearsay rule.

08:31:52 THE COURT: Okay. We need to identify those by exhibit number.

MR. MANKOFF: The Grassi paper, I mean, there's several versions so I'm not sure which versions the defendants

08:32:03 have proffered, but I believe it is 7312.

MR. NORTH: Yeah, I think that's right.

MR. MANKOFF: And then the monthly report is 4327.

THE COURT: All right. I don't remember what the issues are on the Grassi paper. Is that the SIR guideline?

08:32:26 MR. NORTH: Yes, Your Honor. That's what it is.

THE COURT: That's what we talked about last night.

Okay. So last night Mr. Lopez said he was going to think about the question of whether both ought to come in simply for notice and not for the truth of the matter

08:32:39 asserted, and he was going to respond this morning.

What are your thoughts on that?

MR. MANKOFF: So we don't agree they should come in for notice. As far as the SIR guidelines, the purpose that they're trying to use them for is to show that they complied

08:32:56 with the rates that are listed in tables 2 and 3. And so if they wanted to just say they sent the SIR guidelines to the FDA and show the cover page, that would be acceptable. But the information in those tables is actually embedded hearsay within hearsay within hearsay because it comes from citations

08:33:20 to a number of other medical articles. And when you look at

those medical articles, they're summarizing information from even more medical articles going back in time. And there's been no showing that any of those are not hearsay.

THE COURT: All right.

MR. NORTH: Your Honor, as the Court mentioned, you proposed an agreement last night. We were initially told the agreement was acceptable, that both documents could come in. We were later told there had been a change of mind.

We believe the Court discussed yesterday that the last four pages of that report that summarized -- that they want to offer that summarizes complaint files is clearly hearsay within hearsay as far as reports of what the doctors said, what the sales rep heard, what the marketing person heard or found out. So the question is does it come in on notice as they have proposed. I think that's a close call.

I think it's less a close call as to whether the SIR guidelines come in on notice. We have cited several cases that have found that learned treatises can, in fact, be admissible as substantive evidence because they're not being offered for the truth of the matter asserted when they're generally just being introduced to show the general knowledge or notice of the medical community.

And we have outlined that in the trial brief we filed very early yesterday morning.

I think my ultimate point is it seems to me that if

08:34:52 their document 4237 or 4327, I get that mixed up, comes in on the issue of notice, then the SIR guidelines should come in as substantive evidence on the issue of general knowledge or notice to the medical community. So --

08:35:12 MR. MANKOFF: I understand that you proposed a quid pro quo yesterday, but the issues are actually distinct. So just because one might be notice doesn't mean that the other one qualifies in the same way.

The MDR reports are -- the reports are regularly

08:35:28 conducted in the ordinary course of business, and we laid that foundation. Now I understand that you're saying that some of the information may have come from doctors.

But the Ninth Circuit *Childs* case and *Reilly* case

08:35:46 stand for the proposition that where that information is there's a duty to report it and it's relied on by the party and investigated by them, then it satisfies the exception.

THE COURT: Those cases have never been mentioned before. What are those cases?

MR. MANKOFF: So the *Childs* case involved --

08:36:04 THE COURT: Just give me the citations, is what we with need.

MR. MANKOFF: Okay. So *Childs* is F.3d 1328.

THE COURT: Well, what F.3d.?

MR. MANKOFF: Oh. Sorry. 5 F.3d 1328.

08:36:24 THE COURT: And what page cite?

08:36:28 MR. MANKOFF: 1333.

THE COURT: Okay.

MR. MANKOFF: And *Reilly* is 33 F.3d 1396, page 1414. I apologize, I misspoke. That's a Third Circuit

08:36:40 case.

THE COURT: Which one is Third?

MR. MANKOFF: *Reilly* is the Third Circuit case.

THE COURT: And the first one is a Ninth Circuit case?

08:36:52 MR. MANKOFF: Correct.

THE COURT: All right. Well, I've never had those cites given to me before, so we've obviously not looked at those cases. I did look at the cases that the defense cited, particularly the *Buttice*, B-U-T-T-I-C-E, *versus G.D. Searle*

08:37:15 case, which does reflect what Mr. North said it did. We'll need to look at those cases.

As I indicated to Mr. Lopez last night, my view is that the last four pages of 4327 include at least four different categories of hearsay within hearsay. And I haven't

08:37:42 read these authorities and how they deal with that, so I don't know what they say.

I don't agree with the argument that they don't contain hearsay within hearsay, which is what has been argued so far. I can't remember if it was said at sidebar or in the

08:37:54 court, but those four categories are that there are some

08:37:58 statements in this exhibit from DM. It says DM report. There's been no evidence as to who or what DM is.

There are quotes from doctors where it says the doctor reported this or the doctor said this. That is clearly 08:38:12 hearsay within hearsay.

There are reports from representatives that appear to be based on what the doctors told them because they will say things like, the doctor had difficulty during deployment, the doctor encountered resistance, the doctor did this or that. I 08:38:29 don't know how the sales reps got that except from the doctors.

And then there are some direct reports from doctors recounted where it says "a doctor reported." Those are all hearsay within hearsay. I haven't been able to reach any 08:38:45 other conclusion than that.

As I said to Mr. Lopez, I wrestle with the notice argument because it seems to me the relevancy of the company being on notice only exists if these are true statements, if they're taken for the truth of what's asserted in them. So I 08:39:04 don't know how you divorce relevancy from truth of the matter asserted. But I'll look at these cases and see what they say.

I have the same issue on notice with the SIR guidelines. I think they are relevant only if you accept the reported rates as true, as accurate.

08:39:22 I do understand what is said in the *Buttice* case and

08:39:29 I will think about that, but I think I've got to look at these two cases to make a decision.

MR. MANKOFF: If I could just make one factual point.

The statements in those last four pages of 4327, they
08:39:40 match the statements in the -- what we call the MDR reports, the reports that the company compiled and investigated and they're under a duty to investigate and report to the FDA.

And we have the exhibit numbers of that, that show that they match. And perhaps we'll need to show that.

08:40:01 THE COURT: Well, I can only base admissibility rulings on information in evidence.

MR. MANKOFF: To get them in evidence to show that. But I just wanted to raise that issue that that is further indicia of reliability of those statements.

08:40:14 THE COURT: Well, nobody's been arguing the reliability issue, I don't think. It's just been a matter of hearsay within hearsay.

When you say they match, are you saying they match word for word some other document?

08:40:26 MR. MANKOFF: Correct.

THE COURT: Those other documents are not in evidence, though; right?

MR. MANKOFF: Right.

THE COURT: And there's been no testimony about them.

08:40:33 MR. MANKOFF: So there has been some foundation about

how the MDR reports are handled, that they are investigated and reported to the FDA.

THE COURT: Okay.

Mr. North.

MR. NORTH: Your Honor, I would just like to briefly address the Court's notion or statement a moment ago that the problem you had with the SIR guidelines and the truth, that they're only relevant if those statements are true. I would take a different position on that view, Your Honor.

We are not saying that the actual -- for example, the guidelines say that fracture is reported 2 to 10 percent of the time in the cases. That's the table, 2 to 10 percent. We are not saying or suggesting or using that SIR guidelines to suggest that the actual fracture rate out of all of the universe of filters is 4 percent, 8 percent, or whatever, within that range or even above or below that range.

What we are showing is that the general understanding and knowledge and notice in the medical community is that fracture occurs at some level and doctors still consider it acceptable to continue using filters.

And on that basis we believe it does show the general knowledge of the medical community, and is not being offered to say that that rate, 2 to 10 percent, is the true rate out there.

THE COURT: And tell me, if you would, the relevancy

08:41:59 in your view of that general knowledge in the medical community.

MR. NORTH: I think the relevancy goes to the risk/benefit, Your Honor. That is the heart of this case 08:42:08 under Georgia law as to whether there is a design defect, is whether the risks outweigh the benefits. And this is a major reflection, the understanding in the medical community, that there are risks associated with these devices. And yet they are still acceptable and widely used.

08:42:29 THE COURT: Here, again, is where I'm wrestling. And maybe I'm just not thinking about it clearly. But it seems to me in the risk/benefit analysis, which the jury does, the jury is asked to determine whether the benefits outweigh the risks. It seems to me the jury, then, needs to decide what are the 08:42:45 risks.

And you're asking them, I think, or with this evidence you would suggest to them the risks are fracture at 2 to 10 percent. That's truth of what's asserted in the table.

So that's what I'm wrestling with. I mean, I thought 08:43:03 what you were going to say when I asked you about relevancy is it goes to the failure to warn. If the doctor already knew in the community that it was 2 to 10 percent, then Bard's failure to tell them their rate was within that wasn't a failure to warn. But my question was going to be but what about the 08:43:19 design defect claim and how do we have them not consider it

08:43:22 for the truth of the matter when they're addressing a design defect claim?

MR. NORTH: Well, I agree with, obviously, Your Honor, that it is relevant to the general knowledge of 08:43:32 the medical community for the failure to warn claim. And I agree that, not more difficult, but what requires more analysis is the design defect claim.

I still would take the position that we're not telling this jury and not asking this jury to decide that a 08:43:49 2 percent or -- that the guidelines are saying risk or fracture happens 2 percent of the time or that it's 8 percent or 10 percent. Just that there is a general understanding in the medical community that there is some level of fracture risk, and yet the doctors consider it acceptable to use.

08:44:08 And I think that is evidence, yes, you're right, they've got to make their own risk/benefit calculus. But in doing so, they have to decide if we acted reasonably in choosing the design. If we acted reasonably in putting out a device that had a known level of risk of fracture. And in 08:44:27 that regard I think the reasonableness of our conduct can only be assessed against the framework of the general knowledge of the medical community. And the general knowledge of the medical community is that some level of risk is acceptable, and the SIR guidelines show that without saying that it is 08:44:44 definitely a 2 percent risk or definitely a 5 percent risk.

08:44:49 THE COURT: All right. Well, I've explained why I have difficulty with both exhibits, but I'll read these additional cases and I'll get you a ruling sometime before the close of evidence. I've got to look at those cases, and I
08:45:03 don't know when exactly I'll have time to do that.

Jeff, you're pulling those up? Okay.

All right. Does plaintiff have other matters you wish to raise?

MR. MANKOFF: No, Your Honor.

08:45:11 THE COURT: How about defendants?

MR. NORTH: Nothing, Your Honor.

THE COURT: Okay. You're still planning on --

MR. O'CONNOR: I apologize. I think we do have an issue with Dr. Sobieszczyk that we wanted to bring to your
08:45:24 attention.

THE COURT: You need to get to a mic, Mr. O'Connor.

MR. O'CONNOR: I'm sorry.

We do have an issue about Dr. Sobieszczyk, I believe, that we wanted to raise before he comes on to testify.

08:45:35 THE COURT: What's that?

MR. O'CONNOR: I'm waiting for Joe Johnson, who is going to handle him. I thought he was in the courtroom. I apologize.

THE COURT: Well, we need to address it now. What's
08:45:45 the issue?

08:45:50 MR. O'CONNOR: Is Joe around?

Well, the issue, as I understand it, is going to be that they're going to have a number of different imaging studies to show to the jury, and that they're going to have 08:45:59 Dr. Sobieszczyk testify that those are missed opportunities.

Now, again, the inference here is that there are more doctors who are nonparty at fault. And I know we've been going back and forth on this, but to establish fault of a doctor -- first of all, in Georgia, there has to be notice.

08:46:21 Secondly, to establish the fault of a doctor, you just don't get to say things like it was a missed opportunity. You've got to show that there was a standard of care out there and that it was breached and that the breach caused the injury.

08:46:39 I'll let him take over.

But I -- we know that they are never going to be able to tie all that up. They've missed the notice on the other imaging studies. They are going to try to inject prejudice by maybe calling it a missed opportunity. But the inference they 08:46:59 want the jury to draw is that somehow a missed opportunity of seeing a filter that appears failed in one way or the other caused injuries to Mrs. Booker.

THE COURT: Well, let me ask a question of defense counsel.

08:47:11 What do you intend to present through the doctor on

08:47:14 missed opportunities?

MS. HELM: Your Honor, simply that through the course of her medical -- he is not offering a standard of care opinion. He is going to show that there were -- as we've already briefed and this has been addressed to the Court, that there were three or four opportunities where the imaging showed the condition of the filter. These are the same conditions of the filter that the plaintiff experts, plaintiff's experts, have testified about, and he is going to offer the opinion that those were opportunities to retrieve the filter.

He is not offering a standard of care opinion. We are not offering any of those, other than Dr. Amer, as a intervening cause. But the jury is entitled to know the course of her treatment and to know what the imaging showed along the way.

THE COURT: What is -- what is the relevancy of those other missed opportunities?

MS. HELM: Your Honor, clearly --

THE COURT: What does it go to in terms of the claim or defense in this case?

MS. HELM: It clearly goes to her damages, it goes to the issue --

THE COURT: Okay. Let me have you pause there.

How does it go to her damages? Let's say the jury

was convinced by the testimony there were four missed opportunities in addition to Dr. Amer. How does that have any effect on the damages she can claim?

MS. HELM: Well, Your Honor, it clearly goes to the fact that there's issues that she didn't need the open heart surgery and there were opportunities prior to the surgery to address the filter before the strut migrated to her heart.

THE COURT: Well, are you suggesting that you can argue that because of a missed opportunity -- and I'll make it up -- in 2010, Ms. Booker can't recover for the heart surgery if they find that Bard was the proximate cause?

MS. HELM: No, Your Honor. But I think they can consider that as an intervening cause.

THE COURT: Well, have you ever identified these other doctors as intervening causes?

MS. HELM: Your Honor, we don't have to identify intervening cause under the statute unless we're asking for them to be put on the verdict form. The only nonparty at fault -- and this has been addressed before the Court. The only nonparty at fault who we are asking to have on the verdict form is Dr. Amer.

But as the Court's aware, we don't have to prove fault to show other intervening causes. Under Georgia law, you don't have to prove a violation of the standard of care.

THE COURT: Well, let me interrupt you for just a

08:49:49 minute. It sounds like what you want to be able to argue to the jury in closing is that besides Dr. Kang, there were other intervening superseding causes.

Is that what you want to argue?

08:50:02 MS. HELM: Yes, Your Honor.

THE COURT: How can you argue that if that's not going on the verdict form?

MS. HELM: Well, Your Honor, I actually think maybe the verdict form, as we have it addressed, may have to be 08:50:17 changed from Dr. Kang to other opportunities or other intervening causes.

THE COURT: When did you first notify the defense -- I'm sorry, the plaintiff, that you were going to be arguing that doctors other than Dr. Kang were intervening causes?

08:50:32 MS. HELM: Your Honor, it's clear as a bell in Dr. Sobieszczyk's report that was served months ago. His report and their opportunity to depose him. It's in his report. He talks about over and over again the missed opportunities. We briefed it in the motion in limine. And 08:50:53 all through the motions in limine we discussed missed opportunities. So --

THE COURT: Did you talk about this argument in the motion in limine on intervening cause? I don't remember it. I only remember Dr. Kang being discussed.

08:51:11 You don't have to look it up. I'm just asking for

your memory.

MS. HELM: Your Honor, we definitely discussed missed opportunities in the motions in limine.

THE COURT: Okay. So --

MS. HELM: And that's been a phrase word that we've all been using --

THE COURT: So just so we're clear, the relevancy, then, in your view, of this testimony is that the jury can conclude that one or more of these other missed opportunities was an intervening cause that broke the chain of causation and eliminates Bard's liability.

MS. HELM: Yes, Your Honor. And under Georgia law, under the Supreme Court case in October, we don't have to prove that those missed opportunities were a violation of the standard of care for them to be an intervening cause --

THE COURT: All right.

MS. LOURIE: Your Honor, this is exactly what we discussed yesterday, and my concern about them raising all these other intervening causes, and they sat there and said they did not plan to argue that. That was discussed yesterday.

THE COURT: I don't remember that from yesterday. When was that? How was that discussed?

MS. LOURIE: When we were talking about intervening superseding causes, and I was arguing that by singling out

08:52:20 Dr. Kang, it was a comment on the evidence because they were going to get up and argue, presumably, that there were all these other intervening causes. And you said, well, let's clear this up, and you looked right at them and said, are you
08:52:34 going to be making that argument? And they said no.

THE COURT: Was this last night?

MS. LOURIE: Yes, sir.

THE COURT: I'm afraid it's all become a blur.

MS. LOURIE: I completely understand.

08:52:46 THE COURT: Did you say that last night, Mr. North or Ms. Helm?

MS. HELM: I don't recall saying that, Your Honor.

MS. LOURIE: Well, I would ask that we look at the transcript.

08:52:56 THE COURT: I'll look at the transcript.

Mr. Johnson or Mr. O'Connor, did you want to make any other comments?

MR. O'CONNOR: Yes, Your Honor. And it's this: You know, had we seen this -- on a summary judgment, the ruling
08:53:10 would be reasonable minds couldn't differ on this, because here's the problem: To suggest that to a jury is causing laypeople to speculate, to speculate that somehow the filter was for sure to fail, to speculate somehow that somewhere in the medical community, if that was reported, a decision would
08:53:27 have been made to stop it and pull it out, remove it right

08:53:31 then. It is something that only experts are qualified to talk about and bring to this jury. And that is a flaw in that argument.

THE COURT: Well, but they're going to do this
08:53:43 through an expert.

MR. O'CONNOR: Pardon me?

THE COURT: They're going to do this through an expert, Dr. Sobieszczyk.

MR. O'CONNOR: They're not going to disclose him to
08:53:53 say it would have been removed, they're saying it's a missed opportunity. To take the next step is going to inject and cause this jury to speculate about what would have happened in the medical community in, say, 2009, 2010. Yesterday there was evidence that it wasn't even until 2010 where the medical
08:54:09 community started having heightened awareness.

THE COURT: I understand your point.

Mr. Johnson, you look like you want to say something.

MR. JOHNSON: The only point I wanted to make was that I suspect what's going to happen is we're going to hear
08:54:22 testimony that there are two ways to skin a cat, both of which are within the standard of care. And they want to take that testimony and say that is a missed opportunity to have removed this filter.

From my perspective, they need expert testimony to
08:54:33 say the standard of care would have required the removal of

this filter. They don't have that testimony. And that's why this isn't admissible on the issue of causation.

THE COURT: Well, Ms. Helm, if this doctor says there was a missed opportunity, do you have any evidence that the opportunity that was missed was that a doctor would have removed the filter?

MS. HELM: Yes.

THE COURT: Who's going to give that testimony?

MS. HELM: The expert's opinion is that he would have removed the filter -- that a doctor would have removed the filter. He is entitled to express that opinion.

THE COURT: Is that in his report?

MS. HELM: Yes.

THE COURT: I have to admit this comes as a surprise to me, because up until this morning I don't remember ever hearing the suggestion that the defense was going argue more than one intervening cause.

MS. HELM: Actually, Your Honor, if I may?

THE COURT: Um-hmm.

MS. HELM: In Docket 10258, which is the Court's ruling on the motion in limine, the Court ruled: Defendants may assert the separate legal doctrine of intervening cause with respect to Dr. Kang or other nonparties not named in the notice.

And you further ruled that we did not have to show

that it was fault.

So the issue of --

THE COURT: Well, but do I say anything more than those four words?

MS. HELM: The Court may assert --

THE COURT: Nonparties not named. I mean, did I -- did you argue that I consider others besides Dr. Kang? I don't remember doing that. And I might have, I just -- I know we haven't talked about it in connection with the jury instructions.

MS. HELM: Your Honor, you specifically held, first, with respect with the exception of Dr. Amer, defendants may not assert at trial that other medical providers, including Dr. Kang, should be apportioned under OCGA 511233.

We are not seeking to do that. We are only seeking to -- we have only offered to a standard of care --

THE COURT: I know, on comparative fault --

MS. HELM: And then you said second: Defendants may assert the separate legal doctrine --

THE COURT: That's what you just read; right?

MS. HELM: Yes, Your Honor.

So it was addressed in Motion in Limine Number 6 and ruled on by the Court. That is the motion in limine where we cited *Jordan versus* --

THE COURT: Why is it this hasn't come up in our

discussions of jury instructions on the intervening cause instructions?

MS. HELM: Your Honor, frankly -- I apologize. When we were arguing the jury instructions, I didn't -- it didn't come to my mind. I was not intentionally omitting it, I was focused on the issue at hand. So that's my omission.

THE COURT: When is this doctor going to be put on?

MS. HELM: First up.

THE COURT: This issue gets raised 15 minutes before the doctor comes on.

I mean, you've known about this report a long time, presumably.

Well --

MS. LOURIE: Can we present the Court with the testimony from yesterday --

MR. JOHNSON: No, no, this is the deposition testimony of the witness who is going to be called.

MS. LOURIE: Oh. Sorry.

MR. JOHNSON: May I?

THE COURT: How is this relevant, Mr. Johnson?

MR. JOHNSON: Because he was specifically asked whether he was going to render an opinion as to whether Dr. Kang and the other doctors breached the standard of care with respect to their treatment of Ms. Booker.

THE COURT: Well, but the *Zavala* case says they don't

have to prove a breach of the standard of care.

MR. JOHNSON: But they still have to prove that a doctor -- the standard of care would have required the removal of this filter.

THE COURT: Well, she says that without the words using -- without using "standard of care," this doctor will say had this opportunity not been missed, the filter would have been removed.

Is that in his report?

MR. JOHNSON: I don't believe that's in his report. I think what he is saying is that while I might have chosen to remove it, it would have been appropriate for these doctors not to remove it. That's the problem.

THE COURT: What's in his report, Ms. Helm?

MS. HELM: Your Honor, he specifically calls them missed opportunities to retrieve the filter. His opinion --

THE COURT: And what does he say about that? What is the explanation?

MS. HELM: Well, Your Honor, in his report, that the events that we talk about -- I'm sorry -- he says were missed opportunities to retrieve the filter. He was not deposed -- this was part of our motion in limine. He was not deposed on what that meant at his deposition.

THE COURT: Well, but so the only thing he says is it was a missed opportunity to retrieve the filter?

08:59:19 MS. HELM: He says each of these incidents was a missed -- and that's what you cited to in your order, were that they were a missed opportunity to retrieve the filter.

THE COURT: Okay.

08:59:28 MS. HELM: His opinion is going to be that he would have retrieved the filter.

THE COURT: Does he say that in his report, "I would have retrieved the filter"?

MS. HELM: Your Honor, he doesn't specifically say "I

08:59:37 would have retrieved the filter." He says "These were missed opportunities to retrieve the filter."

THE COURT: Does he say that a reasonable doctor in this situation would have retrieved the filter?

MS. HELM: Your Honor, I think his opinion will be

08:59:50 that -- he doesn't -- no, Your Honor, he does not use those words in the report.

THE COURT: Okay. Then you can't use -- he can't say that in the testimony if it's not in the report.

MS. HELM: Your Honor, I understand. But can he

09:00:02 testify that it's his opinion that the filter could have been removed at the time?

THE COURT: Well, could have been removed. I guess the question is do you have any evidence to this jury that had these opportunities not been missed, the filter would have

09:00:15 been removed? Which, it seems to me, is necessary for any

09:00:19 intervening cause.

MS. HELM: Your Honor, you're asking us to prove a negative because this information was not provided to the medical -- to the treating physicians. That's part of the

09:00:34 problem. He should be able to state within a reasonable degree of medical certainty, which he can, that had this information been conveyed, the filter could have been removed.

THE COURT: Well, let's say -- let's say he says that, and the jury's back in the jury room deliberating and

09:00:50 they say, okay, we have evidence that the filter could have been removed. We don't have evidence that the filter would have been removed. How can "could have been" be an intervening superseding cause?

MS. HELM: Your Honor, in *Moore versus Singh*, 326

09:01:08 Georgia Appeal 805, the court addressed this very issue. In that case one expert offered a standard of care opinion, another expert said this could have happened, and the court ruled that that was sufficient to get the issue to the jury.

THE COURT: Well, we are at two minutes after 9:00 on

09:01:28 the morning we're going to call him and I've never read that case before.

MS. HELM: Actually, Your Honor, you have. It was cited at length and --

THE COURT: On this point?

09:01:35 MS. HELM: Yes, Your Honor. It was cited --

09:01:38 THE COURT: On this issue?

MS. HELM: In the motions in limine.

THE COURT: Were you arguing the "could have" versus "would have" in the motion in limine?

09:01:45 MS. HELM: Actually, Your Honor, I have my --

(The Court and the law clerk confer.)

MS. HELM: Actually, Your Honor, yes, I did argue "could have" in the motion in limine.

THE COURT: Read to me what you wrote.

09:02:19 MS. HELM: "If asked, Dr. Sobieszczyk would have testified that had the condition of her device fracture been discovered and the information been properly reported, Ms. Booker's filter could have been timely retrieved avoiding her complicated surgery."

09:02:34 It is on page 4 of docket 10066, which is our response to their motion in limine. We addressed it head-on.

THE COURT: Well, but that doesn't address the question whether "could have" is sufficient for intervening cause.

09:02:53 MS. HELM: It's sufficient on -- in the *Moore versus Singh* case, they held that the testimony that it could have been done was sufficient to establish proximate cause to get it to the jury.

So, respectfully, Your Honor, this has been briefed

09:03:09 at length and we actually --

09:03:11 THE COURT: No, no, we haven't -- what you're reading me doesn't address whether "could have" is sufficient for intervening cause.

MS. HELM: Your Honor, the *Moore versus Singh* case --

09:03:21 THE COURT: But that wasn't argued; right? Nobody raised the question in the briefing as to whether "could have" is sufficient for intervening cause.

I know you're arguing that's what *Moore* stands for, but I don't think that issue has been raised before today.

09:03:37 MS. HELM: Respectfully, Your Honor, I disagree. I think it's been raised and you held that he could testify to that for --

THE COURT: But the basis for that whole motion in limine was not that his evidence will be insufficient to prove

09:03:51 intervening cause. The whole basis for the motion was they can't argue intervening cause because they didn't identify these doctors as nonparties at fault.

And I disagreed with that, because there's a separate doctrine in Georgia for intervening cause. And I concluded

09:04:05 both doctrines apply; one requires notice, the other doesn't. And you could assert intervening cause. But I don't remember anybody arguing his testimony won't prove intervening cause for the non Dr. Kang events.

Am I -- do you think that was briefed and argued

09:04:23 somewhere?

09:04:25 MS. HELM: Yes, Your Honor, because the Court ruled, in Docket 10258, on page 12: The Court will instruct the jury, making clear that the fault or actions of Dr. Kang or similarly situated nonparties may be considered only if the 09:04:41 three elements of intervening cause set forth --

THE COURT: Okay. You've made that the point that the order talks about other potentials, other potential intervening causes. That doesn't consider the question of whether "could have" is enough for intervening cause.

09:04:54 My point is we are five minutes into when his testimony is supposed to be given and I've never read the case law. Well, if I looked at *Moore*, I didn't look at it on this issue.

Jeff, do you have the intervening cause instruction?

09:05:07 MS. HELM: Your Honor, I have a copy.

Your Honor, also on page 10 of his report, Dr. Sobieszczyk states that retrieval should have been considered and then -- in 2007, and it goes on and talks about the missed opportunities to retrieve.

09:05:43 THE COURT: Well, I can't rule on this issue without looking at the case law. I'm not going to keep the jury waiting while I look at the case law. This is not an issue that needed to be raised just before the witness came on.

I think what I'm going to do is I'm going to allow 09:06:00 him to testify. We'll look at the case law while he is

09:06:03 testifying. If I agree with plaintiffs, I will instruct them to disregard that testimony and I will instruct them that there's only one possible intervening cause, which is Dr. Kang.

09:06:15 If I disagree with plaintiff, then we'll probably go with the instructions as they are because defendant hasn't requested a broader instruction.

But I'm not going to keep this jury waiting on an issue we could have raised long before five minutes to 9 09:06:30 o'clock on the morning this doctor is set to testify.

MS. LOURIE: It was raised yesterday, Your Honor, and they clearly said they were not going to do that.

THE COURT: I know. I know that you've said that. I don't remember it. I don't have the transcript. And I can't 09:06:41 get it from this reporter because it was a different reporter, but I'll look at that as well. And if you're right, then I will take that into account. But I don't want the jury waiting while we try to track down Elaine Cropper in another courtroom, get her out of the courtroom, ask her to go find 09:06:55 the transcript and get it to me, which would take a long time.

Okay. So we don't keep the jury waiting, we're going to go ahead and let him testify on this issue. And in the meantime, let's look -- we need the citation for that case, Ms. Helm.

09:07:14 MS. HELM: Your Honor, I have a copy of the case.

09:07:16 THE COURT: Would you give it to Jeff.

And, Trish, can you e-mail Elaine and see if she can get us --

THE COURTROOM DEPUTY: I'm doing it.

09:07:25 THE COURT: Okay.

MS. HELM: Your Honor, may I be excused for just a minute before we get started?

THE COURT: Yeah.

Okay. It should be on LiveNote, right? How can I

09:08:59 call it up?

(The Court and the court reporter confer.)

THE COURT: All right. Ms. Lourie, are you here? I found the exchange from last evening that I think you're talking about.

09:10:17 You said this. You said: And then one more point if you don't mind. We anticipate, and I don't know because we haven't heard all the testimony in the case, but we anticipate based on the pleadings and the opening statement that defense is going to argue more than one intervening cause. We think

09:10:35 they're going to argue that Dr. Amer is an intervening cause and they possibly could argue that Dr. Harvey is an intervening cause because he didn't leave the strut in the heart.

I then said: Well, let's find out. Are you going to

09:10:51 make that argument, defense counsel?

09:10:53 And they said: No, Your Honor.

And then I said: You are only going to argue Dr. Kang as an intervening cause; is that right?

And Ms. Helm responded: Correct. We're going to
09:11:09 argue that Dr. Amer is a separate act of negligence that impacted Ms. Booker's proximate cause.

So you were talking about Dr. Harvey. But I did ask you, Ms. Helm, I said: You're only going to argue Dr. Kang as an intervening cause; is that right?

09:11:32 And you said: Correct. We're going to argue that Dr. Amer is a separate act of negligence that impacted Ms. Booker's proximate cause.

MS. HELM: Your Honor, I understand my statement. I -- at the time I didn't -- I was thinking about Dr. Harvey
09:11:48 and Dr. Kang. I apologize. I wasn't trying to mislead. I frankly was focused on the issue immediately above that.

THE COURT: Well, the argument you made, Ms. Lourie, was that they would argue Dr. Harvey was an intervening cause. I understand now you probably intended that more broadly, but
09:12:07 that's what's said.

So I can't conclude from that exchange that it was absolutely ruled out. I think that is ambiguous.

MR. STOLLER: Your Honor, in fairness, if there had been anything from the other side alerting us to this, we
09:12:20 would have raised the point at that time because the

09:12:23 particular language in the instruction is limited to Dr. Kang. That's the issue we have here, is that we thought this was a settled issue leaving the courthouse yesterday, that the only intervening cause we're dealing with was Dr. Kang.

09:12:35 THE COURT: I can understand why you reached that conclusion. I don't think that's unreasonable. But given the fact the argument was they're going to argue Harvey as intervening cause, and that's what prompted the exchange, I can't conclude the defendants were thinking and saying we

09:12:50 won't argue the Sobieszczyk -- I don't know how it is pronounced, but this other doctor's testimony.

So I think we need to go forward as I described. We're going to hear the testimony, we're going to look at the case law in the meantime, and I'll make it clear to the jury

09:13:03 at the end if I agree with plaintiff.

But I'm not going to keep the jury waiting while I go do legal research. We're already 15 minutes overdue.

So let's bring them in.

(The jury entered the courtroom at 9:13.)

09:14:30 THE COURT: Good morning, ladies and gentlemen. Please be seated.

We apologize for keeping you waiting 15 minutes. We've been in here working since 8:30 in an effort to get things clarified so we can get through the evidence, we hope,

09:14:41 today. And we're sorry we kept you waiting during that time.

09:14:44 Okay. We are going to proceed with the defense testimony.

MS. HELM: Your Honor, at this time -- and I can't pronounce his first name, so I'm not even going to try -- we
09:14:53 call Dr. Sobieszczyk.

THE COURT: All right.

Sir, would you please come forward, please.

THE COURTROOM DEPUTY: If you would stand right here and raise your right hand.

PIOTR SOBIESZCZYK, M.D.,

called as a witness herein, after having been sworn or affirmed, was examined and testified as follows:

THE COURTROOM DEPUTY: Doctor, would you mind please spelling your name for the record.

09:15:07 THE WITNESS: P-I-O-T-R, last name is S-O-B-I-E-S-Z-C-Z-Y-K.

THE COURTROOM DEPUTY: Thank you.

MS. HELM: Your Honor, before we proceed I would like to admit into evidence certain medical records of Ms. Booker.
09:15:55 They're Exhibits 6827, 6826 --

THE COURT: Hold on, if you would, just one minute, please.

MS. HELM: I'm sorry.

THE COURT: Okay. Say those again.

09:16:15 MS. HELM: 6827, 6826, 6822, 6823, and 6710.

09:16:27 THE COURT: Any objection?

MR. JOHNSON: Judge, those are excerpts from large imaging studies. I would prefer that the entire imaging study be admitted into evidence as opposed to just these select 09:16:39 portions of those studies.

THE COURT: What's your response, Ms. Helm?

MS. HELM: Your Honor, it's impossible to show the entire imaging. We'll be happy to tender the discs into evidence.

09:16:50 THE COURT: How large are those studies, Mr. Johnson?

MR. JOHNSON: Judge, I don't know how large they are, but as the Court probably knows, a CT imaging study consists of many, many, many separate images. And to pull one image out to the exclusion of the other is, I think, a little 09:17:06 misleading. They can certainly isolate those for purposes of the doctor's testimony, but I would prefer that the entire study be admitted as opposed to a single image.

THE COURT: Well, I'm going to go ahead and admit these exhibits with the proviso that if you all can reach 09:17:18 agreement, we will put the rest of it in, and I'll be happy to rule on that if you can't reach agreement. So I'm not foreclosing the opportunity, but I'm going to let them introduce these exhibits.

MR. JOHNSON: Okay.

09:17:30 MS. HELM: Your Honor, I don't think there's any

dispute. We'll be happy to tender the entire set of images, tender the entire discs into evidence.

THE COURT: Okay. We'll deal with that when we're not keeping the jury waiting on that issue.

MS. HELM: Thank you.

(Exhibits 6710, 6822, 6823, 6826 and 6827 admitted.)

D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Dr. Sobieszczyk, you heard me say I can't pronounce your first name. Would you please introduce yourself to the jury.

A Good morning. My name is Piotr Sobieszczyk. It's a Polish name, hence difficult. I am a practicing cardiovascular specialist at Brigham and Women's Hospital and Harvard Medical School in Boston.

Q Would you please tell the jury where you're originally from?

A I was born in Poland, and came to the United States when I was a teenager.

Q And what were the circumstances that brought you to the United States?

A At that time Poland was still under communist rule, and my parents left and took us with them for political reasons.

Q Did you go to high school or graduate from high school in the United States?

A I did.

09:18:35 Q And did you go to college in the United States?
A Yes.
Q Where did you go to college?
A I went to college at Harvard College in Boston.
09:18:44 Q And did you receive a degree from Harvard?
A Yes, I did.
Q And what is your degree from Harvard?
A It was bachelor of arts in biochemistry.
Q And following college, did you go to medical school?
09:18:58 A Yes. I moved to New York City and attended Columbia University Medical School.
Q Did you graduate from Columbia Medical School with honors?
A Yes, I did.
Q Tell us about your formal training following medical
09:19:10 school.
A I moved back to Boston and completed residency in internal medicine at Massachusetts General Hospital. And from there moved across town to Brigham and Women's Hospital, where I completed training in cardiology, followed by additional
09:19:30 training in vascular medicine, and then completed additional fellowship in interventional cardiology and also in additional interventional training in diseases or in blood vessels, veins or arteries, outside the heart.
Q Do you currently hold any academic appointments?
09:19:58 A Yes. I am -- I have a teaching appointment at Harvard

09:20:04 Medical School.

Q And what do you teach?

A I teach cardiovascular medicine, vascular medicine, to residents and fellows. And also procedures in the heart 09:20:20 arteries, heart valves, and blood vessels in the body to advanced fellows.

Q Does that include the implantation and retrieval of IVC filters?

A Yes, it does.

09:20:32 Q Do you also practice, actively practice medicine?

A I am -- I practice at Brigham and Women's Hospital, yes.

Q And is Brigham and Women's Hospital affiliated or associated with Harvard Medical School?

A Yes. It's one of the major teaching hospitals of that 09:20:51 medical school.

Q Do you hold any leadership positions in your interventional cardiology practice?

A So within the scope of my practice I am an associate director of the cardiac catheterization laboratory, and I'm a 09:21:05 director of the vascular diagnostic laboratory at Brigham, where we perform ultrasounds of veins and arteries to diagnose vascular disease.

Q I should have asked this previously. Are you licensed to practice medicine?

09:21:22 A I am.

Q And in what state?
A In Massachusetts.
Q Have you been certified by any boards of medicine?
A Yes. I was -- I took board examination in internal medicine, cardiovascular medicine, and interventional cardiology, and passed those boards.
Q Approximately how long have you been practicing medicine?
A I started my residency in 1997, so it's just about 20 years.
Q All right. As part of your interventional cardiology practice at Brigham and Williams, do you work with IVC filters?
A I do.
Q Approximately how many IVC filters do you estimate you have implanted and retrieved over the course of your medical career?
A I don't know the exact number, but it's well over hundred.
Q Does that include Bard filters?
A It does.
Q Does that include other manufacturers' filters?
A Certainly.
Q And does that include the Bard G2 filter?
A It did, yes.
Q Have you treated and followed patients who have had filters implanted and/or retrieved?

09:22:25 A Yes.
Q In preparing your opinions in this case, did you review the medical records for the plaintiff, Ms. Booker?
A I have, yes.
09:22:35 Q Did your review of the medical records include reviewing X-rays, CT scans, and other imaging of Ms. Booker?
A It did.
Q Doctor, before we get to your opinions, in the records of Ms. Booker that you reviewed, did you see an indication that
09:22:54 she had experienced a heart attack or heart attacks prior to receiving her G2 filter?
A There was a mention of that in the admission note when she presented with her pulmonary embolism, yes.
Q And you -- am I correct that you have not had an
09:23:11 opportunity to go back and look at the actual medical records relating to that diagnosis of a heart attack?
A No. Those records were not available.
Q At the time Ms. Booker received her filter in 2007, had she experienced prior pulmonary embolism?
09:23:30 A According to the admission note, yes, she suffered pulmonary embolism a few years before that presentation.
Q And she had also suffered a pulmonary embolism approximately a month before the implant; is that --
A That is correct.
09:23:44 Q And at the time she was admitted at New York Methodist

09:23:49 Hospital for the implant of the filter, was she taking anticoagulants?

A At that time she was treated with blood thinners, anticoagulants, for the pulmonary embolism, yes.

09:24:08 Q Based on your review of the medical records, did she have to stop taking the anticoagulants when she was admitted to New York Methodist in June of 2007?

A Yes.

Q And why did she have to stop taking the anticoagulants?

09:24:18 A She developed bleeding complication and her hematocrit decreased and she developed anemia, and so the blood thinners had to be stopped.

Q Dr. Streiff testified in this case that a patient with a pulmonary embolism approximately a month before the implant of

09:24:36 the filter, an active bleed who had to stop anticoagulants and was diagnosed with cancer, is an appropriate candidate for an IVC filter.

Do you agree with that?

A I do.

09:24:48 Q Do you agree that Ms. Booker was an appropriate candidate for an IVC filter?

A Yes.

MS. HELM: Can we pull up 6827.1, please.

BY MS. HELM:

09:24:59 Q Doctor, can you see this image on the screen?

09:25:05 A Yes, I can.
Q Can you tell the ladies and gentlemen of the jury what this is?
A This is a scout radiograph performed as part of a CT scan
09:25:15 on June 21st, 2007. So it is basically an X-ray which is performed in the initial stage of obtaining a full CAT scan, and it's used as a bird's-eye view image to time and determine which part of the body's going to be imaged by the CAT scan.
Q Wait, Doctor, let me interrupt you.
09:25:39 MS. HELM: Your Honor, this has been admitted. May it be published to the jury?
THE COURT: Yes.
MS. HELM: Thank you.
BY MS. HELM:
09:25:47 Q Dr. Sobieszczyk, is this the scout scan of the CT that was taken the day after Ms. Booker's filter was implanted?
A Yes.
Q And would you show the jury -- you don't have a laser pointer?
09:26:05 A I do not.
Q Does the -- we're --
THE COURTROOM DEPUTY: He can write on the screen.
BY MS. HELM:
Q You can circle on the screen, you can show the jury
09:26:12 where --

09:26:13 A So in the circle you can see the actual filter. On the upper part of the circle you may notice a brighter white tip of the filter, which was more visible, and the same image somewhat enlarged is on the right part of the -- of the slide.
09:26:37 And you can see that the filter is straight up and down along the vertebral column in the IVC without any evidence of tilting. And this is right after placement of the IVC filter.

MS. HELM: You can take it down.

BY MS. HELM:

09:27:00 Q At the time Ms. Booker's G2 filter was implanted in June of 2007, do you have any understanding about whether that filter was cleared for permanent or optional use?

A At that time the filter was cleared for permanent use.

Q Back in 2007, were you retrieving G2 filters that had --
09:27:18 before they were cleared for retrievability?

A Yes.

Q Are you aware that Dr. D'Ayala, who implanted the filter, testified that he wanted a retrievable filter?

A Yes, I am.

09:27:31 Q Did you agree -- do you agree with that assessment for Ms. Booker?

A Yes.

Q Are you also aware that Dr. D'Ayala testified that it was important for Ms. Booker to return for follow-up regarding her
09:27:41 filter?

09:27:42 A Yes.
Q Doctor, do you have an opinion as to whether Ms. Booker's filter should have been retrieved in 2007 or 2008?
MR. JOHNSON: Disclosure, Your Honor.
09:27:54 THE COURT: Is this in the report?
MS. HELM: Yes, Your Honor, page 10 --
THE COURT: Could I have a copy, please.
MS. HELM: Your Honor, I provided a copy.
THE COURT: Okay.
09:28:04 MS. HELM: Page 10, opinion number 1, "The filter would have been retrieved once anticoagulation was resumed and tolerated."
THE COURT: Where on page 10?
MS. HELM: Paragraph -- opinion number 1.
09:28:33 THE COURT: Page 10 doesn't have a opinion number 1.
MR. JOHNSON: Page 11, Your Honor.
MS. HELM: I'm sorry.
THE COURT: Okay.
MS. HELM: My copy, for some reason it's page 10.
09:28:43 Opinion number 1.
THE COURT: All right. Let me read that.
Would you please rephrase the question.
MS. HELM: Yes, Your Honor.
BY MS. HELM:
09:29:18 Q Dr. Sobieszczyk, after Ms. Booker's biopsy for her

09:29:24 cervical cancer in 2007, would you have resumed her anticoagulation therapy?

A I would have, yes.

Q And if that anticoagulation therapy had been resumed,

09:29:41 would you have recommended that the filter be retrieved?

MR. JOHNSON: Same objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: I would have.

BY MS. HELM:

09:29:54 Q And if anticoagulation therapy could not have been resumed, would you have still recommended that the filter be retrieved?

A I would have waited for six months, which is the usual treatment for pulmonary embolism deep vein thrombosis with

09:30:13 blood thinners, and when that time period was completed, I would have retrieved the filter.

Q Do you see any evidence from the medical records for Ms. Booker that you reviewed that retrieval of the filter was considered before 2014?

09:30:30 A Not in the records I reviewed.

Q Doctor, in review of the records and imaging, did you identify times where you felt like there were signals that the filter should have been retrieved?

A Yes, I have.

09:30:47 Q And do you refer to those as missed opportunities?

09:30:50 A I think you could call them that, yes.
Q What do you mean by a missed opportunity?
A I think there are several imaging studies which provide information that the filter changed its position, and those
09:31:09 imaging studies should have prompted reconsideration and consideration of filter retrievable.
Q And when was one of those first -- when was the first missed opportunity?
A I believe the first one was in February of 2008.
09:31:29 MS. HELM: Would you please pull up 6827.003.
BY MS. HELM:
Q Your Honor -- excuse me. Dr. Sobieszczyk, can you explain to the jury what this image is?
A Yes. This is an actual CAT scan obtained on
09:31:47 February 24th, 2008, and you can see here the vertebral column. And in bright white you can see parts of the filter struts. The circle in gray here is the aorta, and you can see a bright white line right over the vertebral column, which extends out of --
09:32:18 THE COURT: Ms. Helm, he's drawing on the screen, but this is not in front of the jury.
MS. HELM: Your Honor, I apologize. May it be published, please?
THE COURT: Yes.
09:32:25 MS. HELM: I apologize.

09:32:30 THE WITNESS: So the striking feature or finding here is that you can see -- and I'll draw another arrow here -- you can see that one of the filter struts extends out of the IVC towards the gray circle, which is the aorta. And this filter
09:32:53 is tilted and one of the legs extends out of the IVC and touches on the aortic wall.

BY MS. HELM:

Q Dr. Sobieszczyk, did you also review the written report relating to the CT scan?

09:33:08 A I have.

Q And did that report indicate whether there was any foreign body in Ms. Booker's right ventricle or in her heart?

A No.

Q In March of 2008, when this CT scan was taken, could
09:33:24 Ms. Booker's filter have retrieved percutaneously?

A I believe it could have.

Q Let's go on to the next missed opportunity. Do you recall when that was?

A I believe it in was March of 2009.

09:33:42 MS. HELM: Could you please pull up 6825.003.

Your Honor, this was previously admitted. May it be published?

THE COURT: Yes.

BY MS. HELM:

09:34:05 Q Would you explain to the ladies and gentlemen of the jury

09:34:06 what this is, please?

A Yes. This is an X-ray of the lower spine, lower vertebral column, which you can see here. To the left of it you can see the IVC filter. And the important finding here is that one of

09:34:27 the struts or arms of the filter, rather than pointing down, is now pointing straight up. It's fractured.

And another finding here is that here is another fragment, this one. If you trace it all the way up, you can see that it ends right here, and it's no longer connected with

09:34:50 the tip of the filter, just like the other legs.

So you have two fragments or two pieces of the filter which are no longer attached to the tip of the filter.

MS. HELM: Scott, would you pull up 6825.4, please.

Your Honor, this is another image of this that's been

09:35:15 admitted. May I publish it?

THE COURT: Yes.

BY MS. HELM:

Q Dr. Sobieszczyk, is this an enlarged view of the X-ray we were just talking about?

09:35:24 A Yes, it is.

Q Does this show more clearly the fractures or the separations that you had previously discussed?

A Yes. You can again see the strut pointing up rather than down and it's separated from the tip of the filter. And,

09:35:41 again, you can see the leg -- I'm sorry, the other fragment

right here, and you can see that it ends at this level and it's also not connected to the circled tip of the filter.

Q Doctor, did you have an opportunity to review the X-ray report, the written report, about this X-ray?

A Yes, I did see it.

MS. HELM: Would you please pull up 6668.

Your Honor, this was previously admitted. May I publish?

THE COURT: Yes.

BY MS. HELM:

Q Dr. Sobieszczyk, would you explain to the jury what this is?

A This is the radiologist's interpretation of the X-ray we just reviewed and the official report of the study.

Q And what does the radiologist say about the condition of the filter in this X-ray report?

A The report reads that the IVC is noted. But it does not comment on its location or condition.

Q The report does not mention that it's fractured?

A It does not.

Q The report does not mention that one of the struts is pointing in the opposite direction of the others?

A No.

Q As a treating physician, when you receive an X-ray report such as this, how would you interpret the words "IVC filter is

noted"?
A I would have assumed that it's in the IVC and it looks fine.
Q Doctor, even though the filter is fractured, is it your opinion that the entirety of the filter is present --
MS. HELM: Would you go back to 6825.004, please.
And, again, Your Honor, may I publish?
THE COURT: Yes.
BY MS. HELM:
Q Doctor, let me ask it again since I got caught in my publishing.
Even though the filter is fractured, is it your opinion that the entirety of the filter is present in this image?
MR. JOHNSON: Leading, Your Honor.
THE COURT: Sustained.
BY MS. HELM:
Q Dr. Sobieszczyk, would you tell the ladies and gentlemen of the jury what you can see about the filter in this image?
A I believe that the filter is otherwise intact. That is, all of the fragments of the filter are accounted for in this image.
Q In March of -- on March 26, 2009, could Ms. Booker's filter and the fractured struts have been retrieved percutaneously?

09:38:21 A I believe that they could have been, yes.
Q Let's discuss one more missed opportunity.
MS. HELM: Would you please pull up 6826.001.
Again, Your Honor, this is admitted. May I publish?
09:38:42 THE COURT: Yes.
BY MS. HELM:
Q Dr. Sobieszczyk, this is another one of those blob images. Would you explain to the jury what this is, please?
A Absolutely. So this is another CAT scan of the abdomen,
09:38:51 which was obtained in December of 2011. And here the image slices start a little bit above the diaphragm and we're basically looking at the slices going from top to bottom. You can see the vertebral column here, the IVC with the bright dots being the legs of the filter is in the circle here, and
09:39:23 in this circle here you can see the kind of white-gray circle, that's the aorta. And what you can also see is that there is a bright white line extending from the direction of the IVC towards the aorta, and that's this strut that we previously saw touching the aorta. It is now well within the lumen or
09:39:52 within the aorta. It's entered the vessel.
Q And, Dr. Sobieszczyk, does this CT scan or did your review of this CT scan reveal whether any portion of Ms. Booker's filter was in her heart or in her right ventricle?
A In the visualized parts of the heart, there was no
09:40:14 evidence of any foreign body there.

09:40:17 Q And in December of 2011, when this CT scan was taken, could Ms. Booker's IVC filter and the fractured struts have been retrieved percutaneously?
A I believe they could have.
09:40:41 Q We have heard evidence in this case that Ms. Booker had a strut, a fractured strut from her filter that moved to her right ventricle. Do you know when that occurred?
A I don't know which day exactly this event took place, but we can say that it happened sometime between when this CT scan
09:41:04 was obtained and when another CT scan was obtained in April of 2013, I believe.
Q So sometime between December 2011 and April of 2013 is the best from the imaging that you're able to narrow that down; is that right?
09:41:21 A That is correct.
Q Okay.
MS. HELM: Would you please pull up 6822.001, please. Your Honor, this is admitted. May I publish?
THE COURT: You may.
09:41:39 BY MS. HELM:
Q Dr. Sobieszczyk, is this the CT scan from April of 2013 that you reviewed regarding Ms. Booker?
A Yes. This is the study from April 9th, 2013.
Q And what does this CT -- what is that of and what does
09:41:55 that show?

09:41:56 A In this image we see a cross-section of or slice of the heart here in gray. And what you notice is a very bright line right there. That's the fragment of the filter which here lies along the septum or along the thick wall separating the
09:42:22 right ventricle from the left ventricle, the two pumping chambers of the heart.
Q And, again, that is the first image you saw where any portion of the filter was in the heart; correct?
A That is correct.
09:42:39 Q Let's shift gears.
MS. HELM: You can take that down.
BY MS. HELM:
Q Let's talk about the retrieval or removal of Ms. Booker's filter. Do you recall when that occurred?
09:42:48 A That was either took place on June 24th or -- 24th, I believe, of 2014.
Q And that procedure was done by a Dr. Kang in Georgia; correct?
A Correct.
09:43:05 Q Do you agree --
A It was July, I think. Sorry.
Q Do you agree with Dr. Kang's decision to remove the filter percutaneously from Ms. Booker's inferior vena cava?
MR. JOHNSON: Disclosure, Your Honor.
09:43:20 THE COURT: Where is that in the report?

09:43:27 MS. HELM: Page 11, opinion number 3, the first sentence, "The decision" --

THE COURT: I see it.

Objection overruled.

09:43:40 THE WITNESS: I would have not -- sorry. Can you restate the question?

BY MS. HELM:

Q Absolutely. I apologize.

Do you agree with Dr. Kang's decision to retrieve

09:43:50 Ms. Booker's filter percutaneously?

A The filter, yes. I do.

Q And do you agree with Dr. Kang's decision to attempt to retrieve the struts that were still in her inferior vena cava percutaneously?

09:44:06 A I do.

Q Was the filter itself successfully removed by Dr. Kang percutaneously?

A Yes, it was.

Q And would you -- the jury has heard, but would you remind

09:44:16 the jury what "percutaneously" means?

A Yes. Percutaneously means essentially that you are doing a procedure without making an incision in the skin and, rather, entering the body through a needle or -- and then if you place a wire through a needle and over that wire when you

09:44:37 get into the artery or vein, you place a little tube which

allows you to then advance different equipment or devices into the vessels. So you're going through the skin percutaneously, but without making a surgical incision with a scalpel.

Q Your Honor -- I mean Dr. Sobieszczyk, the strut that Dr. Kang was able to retrieve from Ms. Booker's filter percutaneous- -- from her IVC percutaneously, was that the strut that was perforating her abdominal aorta?

A I believe that's the case.

Q And would you anticipate her having any further -- any issues relating to that strut perforating the abdominal aorta?

A I do not.

Q Were there any complications with the retrieval of the filter and the one strut that Dr. Kang was able to retrieve percutaneously?

A No.

Q Before Dr. Kang retrieved the filter, was it tilted?

A Yes.

Q In fact, we know it had been tilted since 2008; correct?

A That is correct.

Q And before Dr. Kang retrieved the filter, had it perforated the IVC?

A Yes.

Q Until the time of the retrieval by Dr. Kang in July of -- in July of 2014, was Ms. Booker receiving any benefit from the filter even though it had tilted and perforated?

09:46:24 A I think she was, yes.
Q And why -- on what do you base that?
MR. JOHNSON: Disclosure, Your Honor.
MS. HELM: His deposition, page 104, lines 13 to 25,
09:46:36 Your Honor.
THE COURT: Okay. Hold on just a minute.
104?
MS. HELM: Yes, Your Honor.
THE COURT: I think you need to rephrase the question
09:47:02 consistent with the language in the deposition, please.
MS. HELM: Sure, Your Honor.
BY MS. HELM:
Q Until the time of retrieval in 2014, was Ms. Booker
receiving any benefit from the filter even though it had
09:47:15 tilted?
A I believe she was.
Q And on what do you base that opinion?
A Well, before the filter was placed, she suffered two
episodes of pulmonary embolism and -- I think five years
09:47:32 before the filter was placed. And after the filter was
placed, we have no clinical evidence that she had any
recurrent pulmonary embolism.
Q Dr. Sobieszczyk, we know that Dr. Kang was not able to
retrieve the strut that was in Ms. Booker's heart; correct?
09:47:55 A Correct.

09:47:56 Q I want to talk about the attempt and the decision to retrieve the filter -- the strut that was in Ms. Booker's heart. In your practice, have you had any patients who have had a strut or a piece of an IVC filter that embolized to the
09:48:12 heart?
A I have.
Q Have you also published a case report on a patient who experienced a fragment of a filter that migrated to the right ventricle?
09:48:26 MR. JOHNSON: Leading, Your Honor.
THE COURT: Overruled.
THE WITNESS: I have.
BY MS. HELM:
Q And in what publication did you publish this report?
09:48:34 A It was in the Journal of Vascular and Interventional Radiology.
Q And do you recall the date of that report?
A I believe it was in 2010.
Q And would you explain to the jury the circumstances, the
09:48:48 medical circumstances of the patient in that study?
A Yes. This was a patient who, several years before she developed this problem in question, had a very large pulmonary embolism which ultimately required a surgical procedure where the blood clots were extracted from the pulmonary arteries.
09:49:14 And as part of that surgery, she received an IVC filter to

protect her from any possible recurrent pulmonary embolism in the future.

Several years later, it was noticed that fragments of that filter had fractured and then moved to the lung arteries and into the right ventricle.

Q And have you followed that patient since 2009 or '10?

A She was followed by one of my partners, and is still followed in our general practice, yes.

Q And are you aware of her current medical condition?

A She's doing well.

Q And does she still have a strut in her right ventricle?

A She has two fragments in her right ventricle.

Q And they've been there for seven years, eight years?

A Almost nine, as far as we can tell, yes.

Q Do you agree with Dr. Kang's decision to attempt to retrieve the strut in Ms. Booker's right ventricle?

A I would have opted for leaving it in place.

Q And why would you have made that decision?

A I think the decision is based on several factors. Number one, my experience that patients can do well with a fragment in the right ventricle. Based on the evidence that the position, orientation, of that filter fragment hasn't changed or moved between the study from 2013 to 2014. And also because of the appearance of that strut and where it is in the heart on a CT scan, which was obtained during the admission

for filter retrieval procedure. And on that study, the filter strut is positioned parallel to the septum, or that wall separating the right -- it's an internal wall separating the right from left ventricle, and it appears to -- and that wall and the entire inside of the heart, you can think of it maybe as the mountains and valleys right outside, and so it's not a flat, smooth wall, it's up and down, the mountains and valleys. And on the CT scan, the strut, again, is parallel to the main -- to that wall, and it's in one of the valleys embedded, or the ends of it are stuck against the mountains.

Q Dr. Sobieszczyk, are you referring to the CT scan taken in June of 2014?

A I'm referring to the CT scan that was obtained in, I believe, July of 2014.

Q Okay.

MS. HELM: Would you pull up 6823.002, please.

Your Honor, this is admitted. May we publish it?

THE COURT: Yes.

BY MS. HELM:

Q Is this the CT scan you're referring to?

A Yes.

Q Is this the CT scan taken of Ms. Booker on July 24, 2014?

A Yes. So the date is here, just to confirm.

And you can see the left ventricle or the main pumping chamber here. This is the right ventricle, and this

09:53:12 here is the septum in gray, that thick wall separating those two chambers.

And what you can see here is part of that gray wall extending into the right ventricle. You can think of it as a 09:53:29 mountain coming up, and right in the middle of that, or in it, you can see a much brighter spot, and that's the end of that filter strut which you saw -- which I showed previously lying alongside that septum, and you can see that that bright end is embedded or, you know, stuck in that piece of muscle, in that 09:53:55 mountain. And if you look at the other end of the -- of that filter, that fragment, which is on the next image --

MS. HELM: Would you go to 6823.003, please.

And, Your Honor, again, may we publish?

THE COURT: You may.

09:54:16 THE WITNESS: You can see here, again, you have a piece of the gray muscle extending into the wider chamber -- I'm sorry, more white-contrast-containing chamber of the right ventricle here, and you can see that inside that muscle you again have a bright dot. That is the other end of the -- of 09:54:42 the filter fragment.

And so it appears to be well wedged in between, into those two muscle fragments right along the septum, and that suggests that this is incorporated into the heart muscle, into the septum, and unlikely to, in my opinion, to go anywhere and 09:55:11 cause any problems. And I think that this finding and the

description of it in the radiologist's report would have made me concerned about the success of such a procedure.

Q Let's look at that radiologist report, if you don't mind.

MS. HELM: Can you pull up 6710, please.

Your Honor, this is admitted. May I publish?

THE COURT: Yes.

BY MS. HELM:

Q Dr. Sobieszczyk, is this the radiologist report from July 24, 2014, that refers to the images we were just discussing?

A Yes, it is.

Q And what does the radiologist who read those CT scans say about the position of the strut in Ms. Booker's right ventricle?

A The radiologist here commented that the ends of the strut are clearly embedded in the trabeculations and that the rest of the length of the strut is, again, parallel to the septum. There's very little contrast around it, suggesting that it's flat against the wall and endothelialized, or incorporated, covered by the inner lining of the heart. And essentially well incorporated into that septum wall.

Q Do you agree with the radiologist's finding in this report based on your review of the CT scan?

A I do. It's also important to note that this wire fragment here on this CAT scan was not interfering with the valvular

09:57:21 structures in the heart.
Q Dr. Sobieszczyk, did Dr. Kang have the opportunity to review this report prior to his attempt to retrieve the strut from Ms. Booker's heart?
09:57:33 A If my timing is correct, I think this was -- this study was performed a day after the retrieval attempt.
Q Without the benefit of the information from this CT scan, would Dr. Kang have been able to fully assess whether the strut was embedded in the heart and whether he could have
09:57:53 successfully retrieved that strut?
MR. JOHNSON: Disclosure and leading, Your Honor.
THE COURT: Where is this in the report?
MS. HELM: Your Honor, the statement in the report regarding Dr. Kang is not there. I'll rephrase the question.
09:58:09 THE COURT: All right. Objection is sustained.
BY MS. HELM:
Q Dr. Sobieszczyk, do you have an opinion as to the likelihood of success or the chances of success of Dr. Kang being able to retrieve the strut percutaneously?
09:58:30 MR. JOHNSON: Disclosure, Your Honor.
MS. HELM: Your Honor, page 11, opinion number 3.
THE COURT: All right, I'll read that.
MS. HELM: The phrase says "so the likelihood" --
THE COURT: Let me look.
09:59:08 MS. HELM: Your Honor, I'll be happy to back up and

09:59:10 ask --

THE COURT: Just rephrase the question, if you would.

BY MS. HELM:

Q The approach by Dr. Kang to attempt to retrieve the strut

09:59:17 percutaneously, would you refer to that as an endovascular approach or a procedure?

A Yes.

Q Do you have an opinion as to the likelihood of success of Dr. Kang attempting an endovascular or percutaneous procedure

09:59:35 to retrieve the strut from Ms. Booker's heart?

A Yes. I would have been concerned that the likelihood of success was very low.

Q Despite that, you understand that Dr. Harvey --

MS. HELM: You can take this down.

09:59:54 BY MS. HELM:

Q -- Ms. Booker's surgeon testified that he was going to retrieve the strut from Ms. Booker's heart through an open procedure if Dr. Kang was not successful. Do you recall that testimony?

10:00:05 A Yes.

Q Do you agree with that opinion?

A My --

MR. JOHNSON: Objection, Your Honor. That's an improper question.

10:00:17 THE COURT: That's a what?

10:00:17 MR. JOHNSON: Improper question.
THE COURT: On what basis?
MR. JOHNSON: Commenting on the opinion of another expert.
10:00:23 MS. HELM: Your Honor, he's not tendered as an expert.
THE COURT: Hold on just a minute.
MR. JOHNSON: Also not in the report, Your Honor.
THE COURT: Pardon?
10:00:30 MR. JOHNSON: It's also not in the report.
THE COURT: All right. The first objection is overruled. I don't think it is commenting on another expert.
And where is the disclosure?
MS. HELM: Page -- I have to check my page numbers
10:00:51 because they're different than yours.
I apologize, Your Honor, I thought I had them all marked.
It's on page 7 of mine. It is probably on page 8 of yours. It's in a paragraph that starts "On July 28th" --
10:01:50 THE COURT: All right. Let me look at that.
MS. HELM: -- and it's the third sentence.
THE COURT: Would you rephrase the question consistent with that sentence. I think your question was a bit broader.
10:02:20 MS. HELM: Yes, Your Honor.

BY MS. HELM:

Q Based on your review of Ms. Booker's medical records, including the records from Dr. Kang and Dr. Harvey, do you believe that there was a clear clinical indication for the surgery that Dr. Harvey performed to retrieve the strut from her heart?

A Well, I would say that in my opinion, in my practice, I would have chosen a more conservative approach and not pushed to have the fragment retrieved.

Q And on what do you base that opinion?

A Again, it's the aspects of her imaging and my experience that I alluded to a little bit earlier. The appearance of this filter strut on that CT scan, the lack of it having moved, the absence of any involvement with the tricuspid valve from this strut. I think these would have been my leading reasons for not pushing forward.

Q And do you have that opinion even though Ms. Booker's heart is beating, even though Ms. Booker is moving around, going through her day-to-day life?

A Yes.

Q And, again, it's your opinion that the strut had not moved and would not move; correct?

A That is my opinion. I think -- yes.

Q Now, what we do know is that Dr. Kang did attempt to retrieve the strut from Ms. Booker's right ventricle

10:04:03 percutaneously; correct?
A We do know that, yes.
Q And we also know that during that attempt he damaged or tore Ms. Booker's tricuspid valve; correct?
10:04:16 MR. JOHNSON: Judge, that's a leading question.
THE COURT: Sustained.
BY MS. HELM:
Q During that procedure, did Dr. Kang tear Ms. Booker's tricuspid valve?
10:04:27 A Yes.
Q Did you see anything in the records to indicate that there was any damage to her tricuspid valve prior to the procedure by Dr. Kang to attempt to retrieve the strut percutaneously?
A No.
10:04:44 Q And did that torn tricuspid valve require a surgical repair?
A It did.
Q And was that part of the repair, part of the surgery that Dr. Harvey subsequently did, the minimally invasive procedure?
10:05:03 A Yes.
Q And would you explain to the ladies and gentlemen of the jury what a minimally invasive procedure means in the context of heart surgery?
A That usually refers to a less invasive way of entering the
10:05:22 chest and accessing the heart. The traditional heart surgery

10:05:27 is performed by opening the breastbone up and gaining access to the chest through a rather large incision. Minimally invasive valve repair, be it --

MR. JOHNSON: Your Honor, I need to interrupt. This 10:05:47 is not in the report.

THE COURT: Ms. Helm?

MS. HELM: Your Honor, he's a cardiovascular surgeon. He's qualified to testify what a minimally invasive --

THE COURT: The question isn't whether he's 10:05:58 qualified, the question is where is it in the report.

MS. HELM: That she received a minimally invasive procedure?

THE COURT: And what is a minimally invasive procedure.

10:06:09 MS. HELM: You know what, Your Honor, I'll just withdraw the question.

THE COURT: All right.

BY MS. HELM:

Q Dr. Sobieszczyk, did you have an opportunity to review 10:06:14 Dr. Harvey's operation note relating to the minimally invasive heart procedure he performed on Ms. Booker?

A Yes.

MS. HELM: Would you please pull up 2361.

Your Honor, this was tendered by the plaintiffs and 10:06:27 accepted into evidence a few days ago.

10:06:30 THE COURT: 2361?

MS. HELM: Yes, Your Honor.

THE COURT: We'll just confirm it's in evidence. My notes show that it is. All right. You may.

10:06:46 MS. HELM: May I publish it, Your Honor?

THE COURT: Yeah. You can.

BY MS. HELM:

Q Dr. Sobieszczyk, is this the operation note from Dr. Harvey's -- or part of Dr. Harvey's procedure notes relating to his surgery on Ms. Booker?

10:06:58 A It is.

Q And this relates to the procedure that took place on July 28th, 2014?

A Yes.

10:07:09 Q And in this note, Dr. Harvey states that he successfully repaired the tricuspid valve?

A Correct.

Q Did he also retrieve the strut from the right ventricle?

A Yes.

10:07:21 Q Did he have trouble finding the strut?

A That's what he indicated, yes.

Q And --

MS. HELM: Would you go to the portion of the report under Findings at the time of the surgery.

10:07:36
BY MS. HELM:
Q Do you see that, where he says there was also a foreign body in the RV. Do you understand that to be right ventricle?
A Yes.
10:07:44
Q And that's where he reports that he removed it?
A Correct.
Q And what did he say about how -- about that wire that he found in the right ventricle?
A Well, he indicated in his report here that it was quite
10:08:04
difficult to find within these trabeculations and that it was embedded, incorporated in the muscle, and it was difficult and that -- you know, if there was anything else left behind, it should be left alone because it's embedded, incorporated in the heart muscle. And he indicated that the risk of going
10:08:33
after it wasn't worth it.
Q Thank you.
Based on your review of the CT scan taken in July -- on July 24, 2014, do you agree with Dr. Harvey's analysis that the piece of wire was embedded in the subvalvular structures
10:08:56
of the heart?
A Well, so it wasn't embedded in the subvalvular structures, it was embedded in the septum. At least on the CT scans. So what he means here is it was under the valve. Subvalvular is under the valve. Beyond the valve. On the other side of the
10:09:19
valve. But, yes, the findings here correspond with his

10:09:23 description of what he saw corresponds with the findings on that CT scan, yes.

Q Thank you.

Have you had an opportunity to review Ms. Booker's
10:09:37 post minimally invasive heart procedure, her medical records since then?

A Yes, I have.

Q And how would you describe her recovery and prognosis since that surgery?

10:09:51 A Well, she had an uneventful hospital stay and went home after four days. As to her overall prognosis, in my opinion, it's actually very good.

Q The jury has heard testimony about a survival rate from a tricuspid valve repair. If the tricuspid valve had not been
10:10:19 damaged by Dr. Kang, would we even be discussing survival rates relating to that repair?

A No.

Q Do you have an opinion as to the survival rate of her tricuspid valve repair?

10:10:34 A I do.

Q And what is that opinion?

A I think that it's very favorable and approaching survival rates of general population her age.

Q Thank you.

10:10:49 Now, Ms. Booker also has a strut retained in or near

her IVC; correct?

A Yes.

Q The strut that Dr. Kang was not able to retrieve percutaneously and left; correct?

A Correct.

Q Do you agree with his decision to leave that strut?

A Absolutely.

Q Have you treated patients who have retained struts from fractured IVC filters in your practice?

A Yes.

Q Do you have an opinion of what the likelihood is, whether that strut would cause any injury to Ms. Booker in the future?

A I think that likelihood is exceedingly low.

Q Overall, what is your opinion regarding Ms. Booker's overall prognosis?

A I think it's very good.

Q Doctor, the opinions you've offered today, have they been offered to a reasonable degree of medical certainty?

A Yes.

MS. HELM: No further questions, Your Honor.

THE COURT: Cross-examination.

MR. JOHNSON: Kate, we don't have these studies in our system. Might we borrow your IT guy?

MS. HELM: That's fine.

C R O S S - E X A M I N A T I O N

BY MR. JOHNSON:

Q Good morning, Doctor.

A Hello.

Q You have not been provided with any documents, internal documents, or information from Bard, have you?

A No.

Q Ms. Helm mentioned a minute ago and told everybody in this courtroom you are a cardiovascular surgeon. You are not a cardiovascular surgeon, are you?

A I'm a cardiovascular specialist, I'm not a surgeon.

Q You are not a cardiovascular and thoracic surgeon; correct?

A I'm not a surgeon.

Q You are not the kind of doctor that Dr. Harvey is; correct?

A Correct.

Q You don't perform the kind of surgery that Dr. Harvey performs, do you?

A I do not.

Q You don't perform open heart surgeries, just so we're clear?

A Correct.

Q You don't perform valve repairs or replacements; is that correct?

10:12:54 A No, it's not. I perform percutaneous valve replacements.
Q But you don't perform open heart surgery of the type that was performed on Ms. Booker?
A I do not.
10:13:05 Q And when you referred to this as minimally invasive surgery, you were referring to the manner of access to the chest cavity; correct?
A That's what -- yes.
Q That is, the incision was in between ribs, the ribs were
10:13:21 spread open, but nonetheless Dr. Harvey had to incise Ms. Booker's heart; correct?
A Yes.
Q So there was nothing minimal about the heart surgery itself. Agreed?
10:13:36 A Well, the access and entry into the heart chest cavity was minimally invasive, according to Dr. Harvey. In that sense, yes, it was.
Q But --
A But the rest of the work inside of the heart is just like
10:13:57 with any other surgery.
Q Very invasive and very complex. Agreed?
A It's complex, yes.
Q And invasive?
A It is.
10:14:07 Q Doctor, to the extent that these folks over here have been

10:14:16 privy to internal Bard documents and information, they know more about the inner workings of Bard than you do; correct?

MS. HELM: Your Honor, object.

THE COURT: What's the basis?

10:14:25 MS. HELM: Your Honor, first of all, it exceeds the scope of the direct, and second of all, it is commenting --

THE COURT: Sustained. It exceeds the scope.

BY MR. JOHNSON:

Q Just so everybody's clear, you are not providing any

10:14:41 opinion that any doctor that treated Ms. Booker, whether it be a radiologist or a treating physician, breached the standard of care with respect to their care and treatment of Ms. Booker. Agreed?

A Agreed. I'm not providing that opinion on that.

10:14:59 Q And that's a big fancy legal term, "standard of care." That simply means that there is no doctor in this case that you rendered an opinion on that has committed medical malpractice or medical negligence. Would you agree?

MS. HELM: Your Honor, I object to this question.

10:15:17 He's commenting on the evidence, and Dr. Sobieszczyk has testified he's not offering a standard of care opinion.

THE COURT: Overruled.

Reask the question, if you would, Mr. Johnson.

MR. JOHNSON: Sure.

BY MR. JOHNSON:

Q Just so we're clear, Doctor, you are not rendering an opinion in this case that any doctor that treated Ms. Booker committed medical malpractice or medical negligence. Can we agree?

A We can agree.

Q And we can agree that different doctors have different approaches to clinical situations. Agreed?

A Agreed.

Q You might decide to treat Ms. Booker different than another doctor, but that doesn't make the treatment by the other doctor wrong or negligent. Would you agree?

A I would agree.

Q With respect to the filter that was implanted, I believe in June of 2007, you understand that was a G2 filter?

A Correct.

Q It was properly placed. You would agree?

A I would.

Q That filter went on to fail in a cascading fashion in the sense that it tilted, there were multiple perforations of the vena cava, there were multiple penetrations into adjacent structures to include the aorta, there were fractures of the filter, and one of those fractures migrated to the right ventricle of Ms. Booker's heart. Would you agree?

A So all of those observations are true, yes.

10:17:06 Q And that happened despite the fact that this filter was implanted and placed the way it was supposed to be placed; correct?

A Yes.

10:17:27 MR. JOHNSON: Are you able to pull up image 6826?

BY MR. JOHNSON:

Q Doctor, you referred to that image earlier in your testimony. Do you remember that?

A Yes.

10:17:47 Q And I believe that image was actually obtained in December of 2011?

A Yes.

Q And that image is below the heart, is it not?

A Yes.

10:17:58 MR. JOHNSON: May we publish this, Your Honor?

THE COURT: Yes.

MR. JOHNSON: I apologize.

BY MR. JOHNSON:

Q That image is below the heart. Agreed?

10:18:07 A Yes.

Q We see multiple structures there. And, if you would, identify the aorta for us.

A The aorta is the gray-white circle within the red circle.

Q And because this image is below the heart, we cannot

10:18:25 definitively determine whether there is a fracture or a metal

fragment in Ms. Booker's heart at this time. Agreed?
A Looking at this CT, we can count the fragments, and so we know that they're all accounted for. And the CT, if I remember correctly, included cuts of the heart which didn't show any fragment there. That's what I would say.
Q Sir, are you not aware of the fact that there was one strut that actually fractured in half, so that there were two struts that fractured but there were three pieces?
A It's my understanding there were one strut that fractured and there were two pieces.
Q There were a total of three pieces; correct?
A Well, down -- at which point in time?
Q You tell me.
A Well, down the road, you can see that there was another leg that broke up and went up to the heart. So --
Q You -- go ahead.
A So there was one fragment, one leg, in the heart and then another strut which broke into two pieces and that fragment was at the level of the IVC around the filter.
Q But because this image does not capture the heart, you cannot definitively tell us whether there is a metal fragment in the heart in December of 2011?
A It is my recollection that looking at the entire CT here, you can actually count all the struts, even the fractured one, and there were 12 here, meaning that they were all at the

level of the IVC, they were all accounted for.
Q You were referring to this particular image. You're not able to count all the struts on this image, are you?
A This single slice, no.
Q Okay.
MR. JOHNSON: You can pull it down.
BY MR. JOHNSON:
Q You told us that these filters are supposed to be implanted percutaneously, and to the extent that there's a decision to remove one of these filters, are they intended to be removed percutaneously as well?
A Correct.
Q All right. That is, they are not intended to be surgically removed by opening up the heart; is that correct?
A Correct.
Q We know that a Dr. D'Ayala implanted this filter. Are you aware of that?
A Yes.
Q Dr. Patel ordered the placement of the filter?
A I believe so, yes.
Q Dr. Kang was the interventional radiologist that, using a percutaneous technique, removed the body of the filter and one of the fractured struts; is that correct?
A That is correct.
Q He was unsuccessful at removing the other fractured strut,

as well as the metal fragment that was in the heart?
A Correct.
Q Can we agree that Dr. Kang never would have had to have performed this procedure had this filter not fractured?
A That is correct.
Q Are you aware that Dr. Harvey and Dr. Langford are heart surgeons and thoracic surgeons?
A Yes.
Q And it was Dr. Harvey who performed the open heart surgery to remove the fracture fragment, the metal fragment that was in the heart?
A Yes.
Q This filter catastrophically failed, didn't it?
A It failed insofar as it fractured and fragments of it went to the heart, yes.
Q Would it be accurate to say it catastrophically failed?
A Well, that depends on what you mean by catastrophically.
Q Let me give some context to my question.

This filter tilted, there were multiple struts that perforated the vena cava, there were three struts that penetrated into adjacent vital structures to include the aorta, there were three pieces that fractured, and one of those pieces went to the heart.

Do you consider that to be a catastrophic failure?
A I consider it to be a failure, yes.

Q Catastrophic?

A For a treating physician, catastrophic usually means when there's a fatal outcome. But fortunately this wasn't the case. But I agree with you that this filter failed, yes.

Q In a big way.

A You could say that, yes.

Q And do you understand that when it was determined that this filter had failed in a big way, there was a joint decision by Drs. Patel, Kang, Harvey, and Langford to attempt to retrieve the fragment in the heart using a percutaneous technique?

A I'm not certain whether Dr. Patel, the cardiologist, was involved in the initial decision-making, but you're correct that Dr. Kang and Dr. Harvey formulated the plan together, yes.

Q A plan to attempt to remove the fragment in the heart utilizing a percutaneous technique?

A That's the case.

Q So all of those doctors got together and developed that plan. Agreed?

A Agreed.

Q And that is an example of what we mentioned earlier where perhaps you might not have wanted to attempt that, but it is not below the standard of care for these doctors to have come up with this game plan and implemented this game plan.

10:24:45 Agreed?
A Agreed.
Q And you also saw in the materials that you reviewed that Ms. Booker herself understandably wanted this metal fragment
10:24:56 out of her heart?
A That's my understanding, yes.
Q She wanted it gone; correct?
A Correct.
Q That's pretty understandable, isn't it?
10:25:04 A I think so.
Q I mean, you wouldn't want a metal fragment in your heart, would you?
A Well, it, you know, depends on the metal fragment. In clinical practice we implant a lot of metal structures and
10:25:17 things in the heart, so sometimes you want a metal fragment in your heart. But in general, I agree that I would have weighed the risks and benefits and likelihood of success, and if it were something straightforward, I would agree that it's nice not to have it, yes.
10:25:36 Q The question really was whether you would want a metal fragment in your right ventricle?
A Well, it depends on whether it would be possible to successfully and in a low risk manner to remove it. It depends on the risk/benefit ratio, but --
10:25:58 Q And you understand Drs. Kang and Langford and Harvey

undertook that risk/benefit analysis in developing their game plan?

A I'm sure they did.

Q And those doctors were faced with a very complex medical surgical situation in developing that game plan. Would you agree?

A I would.

Q And that problem they were faced with was completely different than the assessment you undertook from the comfort of your office, looking at these facts retrospectively. Agreed?

A What do you mean -- yes.

Q Okay.

And just so everybody in this courtroom is clear, you have not formed any opinions that Drs. Patel, Kang, Harvey or Langford breached the standard of care in their treatment of Ms. Booker. Would you agree?

A I would.

Q And that includes their decision to attempt to remove the filter percutaneously. Agreed?

A Agreed.

Q And that includes Dr. Harvey's decision to perform open heart surgery to remove this metal fragment. Agreed?

A Agreed.

Q Doctor, what is pericarditis?

10:27:38 A Pericarditis is inflammation of the sac or surrounding tissue outside the heart.
Q And that inflammation is painful?
A It can be, yes.
10:27:53 Q And in the records you reviewed, did you see where Ms. Booker had hospital admissions for chest pain that was ultimately determined to be caused by her pericarditis?
A She had several emergency room visits for chest pain before and after this surgery. Some of them were
10:28:14 characterized as costochondritis and others were given a diagnosis of pericarditis. Though there were no classic signs of pericarditis, but she was given that diagnosis, yes.
Q Well, let's be accurate about this. Pericarditis is commonly seen in patients who have undergone open heart
10:28:44 surgery. Agreed?
A It is seen in the first few days after heart surgery in many patients. It resolves and is very rare afterwards.
Q You're not able to tell us whether Ms. Booker's pericarditis is going to be a lifelong problem, are you?
10:29:05 A Well, her card- -- no. Pericarditis can come from multiple causes, so everyone is at risk for pericarditis.
Q But in this case, because Ms. Booker had her pericardium incised so Dr. Harvey could gain access to the heart, that would be the likely mechanism by which she has experienced
10:29:31 chest pain and pericarditis. Agreed?

10:29:36 A In the initial postoperative recovery, yes. Long-term, I'm not certain about that.

Q Some people continue to have pain and some people don't, is what you're saying?

10:29:47 A Some people could have continuous daily discomfort after an incision, yes, but it's very rare.

MR. JOHNSON: May I have a minute, Your Honor?

THE COURT: Yes.

BY MR. JOHNSON:

10:30:23 Q Doctor, I forgot to ask you what you're charging for your time.

A $400 an hour.

Q And what have you charged to date?

A I -- at the time of deposition I charged, I believe, 10:30:37 $4,600. I have not submitted my bill since that time.

Q Are you able to estimate for us what the remaining bill is?

A I would estimate that I spent another 15 hours working on this on this -- preparing for this.

10:30:55 Q All right. And you're out here for work, so you travel from Boston to Phoenix.

A Yes.

Q And are you charging by the hour or do you have a daily rate for travel?

10:31:04 A I do not.

Q Don't what?
A I don't have either.
Q How are you going to charge?
A Per hour spent testifying and reading documents and preparing.
Q And you arrived when?
A I arrived yesterday morning.
Q And you intend to leave when?
A Tonight.
Q So you will charge for your travel time as of your departure from Boston yesterday morning and then your arrival back in Boston either tonight or early tomorrow morning?
A I must tell you I'm a horrible businessman. My intention is to charge for the time reading, studying, and preparing, not for the travel.
Q Not while on the airplane?
A No.
Q Okay. Thank you.
A You're welcome.

THE COURT: Redirect?

MS. HELM: Just a few questions, Your Honor.

R E D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Dr. Sobieszczyk, in your practice, do you consult with cardiothoracic surgeons?

10:32:10 A All the time.
Q And do you follow patients who are also treated or operated on by cardiothoracic surgeons?
A That's routine. The cardiothoracic surgeon has the
10:32:22 difficult task of operating and sees a patient after the surgery, usually a month later, but it is the cardiologist who follows patients longitudinally over subsequent years.
Q Are you aware and did you -- in the testimony in this case, Dr. Kang had never attempted to retrieve a strut from
10:32:46 the right ventricle prior to --
MR. JOHNSON: Your Honor, this is beyond my cross-examination.
THE COURT: Overruled.
BY MS. HELM:
10:32:53 Q -- prior to his attempt to retrieve the strut in Ms. Booker's heart?
A I believe -- it is my recollection that was this was the first time he tried this.
Q And are you aware that Dr. Harvey and his partner had
10:33:07 never before seen a situation where there was a IVC strut in the right ventricle?
A I believe that is the case.
Q And is it your opinion that prior to performing surgery on the heart, either percutaneously or an open heart surgery,
10:33:24 that you should weigh the risks and benefits of the success of

that surgery?
A I think that would be standard approach.
Q And in your review of Ms. Booker's medical records, you were asked some questions about pericarditis. Do you recall when the last time was that there was a diagnosis of pericarditis?
A Well, I recall the last cardiology visit raised concern that she actually didn't have pericarditis, but that she had costochondritis, which is inflammation of the cartilage connecting the ribs to the breastbone.
Q So her last treatment with her cardiologist, he found no concerns or no evidence of pericarditis; correct?
A That's what his note indicated, yes.
MS. HELM: Thank you. No further questions, Your Honor.
THE COURT: All right.
Ladies and gentlemen, we will break at this point. We will plan to resume at ten minutes to the hour.
We'll excuse you, Doctor. Thank you.
(The jury exited the courtroom at 10:34.)
MR. JOHNSON: He's not excused; correct?
THE COURT: You're done with your cross. No, recross.
MR. JOHNSON: Even on that new subject?
THE COURT: You could have objected beyond the scope

and you didn't. On the one you did, it wasn't beyond the scope, so there's no recross.

MR. JOHNSON: Okay.

THE COURT: Ten minutes to, we'll be back.

(Recess taken from 10:35 to 10:49. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

All right. Your next witness.

MR. NORTH: Your Honor, at this time the defendants would call their final witness, Mr. Chad Modra.

THE COURTROOM DEPUTY: Sir, if you would please come forward, stand right here, raise your right hand.

CHAD MODRA,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. NORTH:

Q Good morning, Mr. Modra. Could you tell the ladies and gentlemen of the jury by whom you are employed.

A C.R. Bard.

Q And how long have you worked for Bard?

A 17 and a half years.

Q And what is your current title with Bard?

A Continuous improvement leader. Formerly vice president of quality.

10:51:51 Q Tell us what a continuous improvement leader does. What is your job function?
A Because I'm aware of a lot of the different systems of C.R. Bard, I'm involved in identifying and conducting projects
10:52:07 that continuously improve the way we do things.
Q And how long have you been in that present position?
A About three months.
Q And prior to that what was your position?
A Staff vice president of operations.
10:52:25 Q And what did you do in that function?
A I had a number of manufacturing sites where we make all kinds of different products report to me. The quality function reported to me. Different places around the world.
Q Now, at some point in your career with Bard have you
10:52:46 worked directly as an employee of Bard Peripheral Vascular in Tempe?
A Yes.
Q And what was your position at Bard Peripheral Vascular?
A Vice president of quality assurance.
10:52:59 Q And what years did you hold that position?
A 2011 through the end of 2015.
Q And while you have taken on other positions with Bard now, do you still maintain your office at Bard Peripheral Vascular?
A I do. I'm still here in Phoenix.
10:53:21 Q What products do you work on, or did you work on, when you

were at Bard Peripheral Vascular?

A IVC filters; PTA balloons, which are angioplasty balloons; implantable ports for cancer treatment; dialysis catheters; biopsy needles; stents; grafts; artificial vessels.

Q Tell us what your responsibilities were at Bard Peripheral Vascular as the vice president of quality.

A As the vice president of quality, all of the quality function reports to me. And it's broken into several areas. It's field assurance, or the folks that take experiences from customers and complaints from customers. It's quality engineering that develops new products. So they speak to doctors and gather design inputs. And then we have quality systems. So they deal primarily with dealing with regulation. Understanding that, making sure we're complying with procedures that meet the regulation of both FDA and around the world.

Q We've heard earlier about engineers working in the research and development department of Bard peripheral. What is different between them and the quality engineers that would have reported to you?

A Those also report to me as the quality function. There may be more specialized biomechanical engineers, mechanical engineers. They have been trained to work on new designs, interface with customers to understand what doctors want, what patients want. So those still reported to me.

10:55:14 We have other quality engineers in different areas, as I mentioned, that do similar function but maybe deal with complaints or continuous improvement.

Q As the vice president of quality assurance at Bard Peripheral Vascular, were you involved over the years with tracking and trending complication reports regarding various products?

A Yes. Certainly.

Q As part of that function and job responsibility, were you involved in tracking and trending complication reports related specifically to Bard's IVC filters?

A Yes.

Q And was that done on an ongoing basis at the company?

A Yeah. IVC filters, as well as every other products, we have monthly reports. Sometimes even more frequent than that. From how they're performing in the field, we do all -- a pretty elaborate set of trending on all those.

Q Tell us a little bit about your background, Mr. Modra. Where did you grow up?

A In the midwest. Near Chicago.

Q And how long have you been in Arizona?

A Since 2011.

Q And tell us about your educational background.

A I grew up in the midwest, went to Purdue University. Graduated with mechanical engineering degree. Moved out to

the west shortly after with another device company, and have worked in Salt Lake and Phoenix since 1994.

Q Let's talk a little bit more about your work history. After you graduated from college in 1993, what was your first job?

A I was on an engineering development program and I worked in Columbus, Ohio, with baby formula manufacturing. So I learned amazing things there. Spent time for six months learning that, but then moved back to Chicago working on a pharmaceutical for six months, and then I moved out here in '94 working for another division of that company.

Q And what was that company, your first medical device company you worked for?

A Abbott Laboratories.

Q How many years were you with Abbott?

A Seven years.

Q And what sort of products did you work on while you were with Abbott?

A I worked on cardiac catheters. So they're pretty complicated catheters with fiber optics; thermocoil, a temperature measurement device on them; a balloon. Primarily those. And they get placed in the heart to measure different things about the heart.

Q And during your years at Abbott, what sort of job titles or responsibilities did you have with those products?

10:58:22 A I was quality engineering. Quality engineer for manufacture. So I learned a lot about the manufacturing of those devices. I was an internal auditor for a period of time. I wrote softwares. I was a software quality engineer, 10:58:35 so I did programming and testing of software related to those devices.

Q And when did you first move to Bard?

A In August of 2000.

Q And did you go straight from Abbott to Bard?

10:58:54 A I did.

Q And what division or area of Bard did you first work with?

A I worked in new product development quality engineering, which gave me the opportunity to be part of the design of brand-new products. So that was very exciting.

10:59:09 Q But what division was that?

A Oh, I'm sorry. Bard Access Systems in Salt Lake City.

Q The jury's heard a lot about Bard Peripheral Vascular but not about Bard Access. Tell us a little bit about what Bard Access in Salt Lake City does.

10:59:25 A Bard Access is another division of Bard. They handle just different groupings of products, different family of products. Primarily at that time dialysis catheters, catheters that they placed in the lower or upper arm to get cancer drugs into your body, ports which get implanted to do the same thing.

10:59:49 Q And what sorts of positions did you have while at Bard

10:59:53 Access?
A I started as a senior quality engineer, became the quality engineering manager, senior manager, and then director in 11 years there.
11:00:03 Q And when did you leave Bard Access Systems?
A In March of 2011.
Q And is that when you moved to Bard Peripheral Vascular?
A That's correct.
Q And what position did you take when you came to Bard
11:00:17 Peripheral Vascular?
A Vice president of quality at Bard. BPV.
Q Was that a promotion?
A Yes.
Q Is there any particular reason you decided to devote your
11:00:32 career to the field of medical devices?
A Well, I've thought about that a lot and I give advice to young engineers all the time, and I really tell them if you want to make something, there's a lot of places you can make something. If you want to make something that helps people,
11:00:49 there's no better place to do that. Medical devices is a great industry. You can come to work knowing that you've done something good each day. It isn't just about making something.
Q When you started work at Bard Peripheral Vascular, when
11:01:06 did you start working at projects involving IVC filters?

11:01:10 A At the time I transitioned from Salt Lake down to here, my predecessor began transitioning my knowledge of the kinds of products that BPV was required -- or oversaw. So she began giving me information, helping me understand the nature of the 11:01:29 products, the -- what they're used for, the design elements, the key complications, the key benefits, the risk assessment of each of those devices. So it was over a period of months right after I moved here that we had a lot of discussions about that sort of transition. The first really 90 days --

11:01:51 Q Was your predecessor in that role at Bard Peripheral Vascular Ms. Gin Schulz that we've seen by videotape during this trial?

A Yeah, yeah it was.

Q Over the course of your career with medical devices, have 11:02:07 you ever seen any devices that did not carry with it some risk of complications?

A Not in my experience, no.

Q What is the general task or charter of the quality department at Bard Peripheral Vascular?

11:02:36 A The quality department maintains an independent voice, if you will, of overseeing the other departments. They don't report to us but we're part of the team where we need to understand the regulation, understand the latest expectations from regulators, meaning FDA or around the world, and we help 11:03:03 modify procedures, make sure that the procedures are being

11:03:07 executed in the right way. We conduct internal audits of each department. We make sure that they're being followed. And then we investigate those and make corrections if we feel like they're not.

11:03:21 Q As the vice president of that department, did you have a role or responsibility in developing policies and procedures for the quality function?

A Yeah. Certainly. That would be one of my primary jobs is making sure that those policies and procedures are in

11:03:37 accordance with what expectations are.

Q And did you have responsibility to fulfill that role to become familiar with the policies and procedures that had existed in the past, the history of those policies?

A Yes. Yes.

11:04:01 Q Now, we have heard a lot about complaints in this case. Does Bard have policies and procedures that govern how complaints are handled?

A Yes. Quite a few.

MR. NORTH: If you could bring up Exhibit 5691,

11:04:23 beginning on page 12.

BY MR. NORTH:

Q Do you recognize this document, 5691.0012?

A I do. It's the standard we have for complaint handling. The primary standard.

11:04:53 Q And was this created by the company as part of its regular

business practices?
A Yes.
Q And was this policy in effect while you were working there?
A Yes. An earlier version of this was there, yes.
Q And are these policies updated occasionally over time?
A Yes. As we understand more of expectations, as industry learns more about what additional expectations may be had from regulators, from the government, this gets updated fairly frequently.
Q Is it a regular practice of the company to create policies of this nature?
A Yes.
MR. NORTH: Your Honor, at this time we would tender 5691, pages 12 through 32, which are this policy.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit 5691 admitted.)
BY MR. NORTH:
Q Mr. Modra, what is Bard's overarching or ultimate goal for processing incoming complaints?
A It's really about understanding the customer experience. Certainly it's required by regulation, so that's one aspect. But it's really understanding the customer feedback.
And it can be a complaint from something minor to

11:06:33 something more significant, but when you have that information, the goal is to really understand how the product is performing and how you can improve the next generation of product.

11:06:44 So we've always seen it as, you know, yes, it's a requirement, but it's an opportunity to hear what your customers are saying. So that's pretty important.

Q Does the complaint investigation and handling process also permit the company to monitor safety issues that may arise

11:07:02 with its products?

A Yes, of course. The tracking and trending that's done along with this is understanding how people are using the product, how it's performing in those, understanding the safety levels; are there new things that are being discovered

11:07:20 or understood about the product, whether it's safety or performance.

Q Does this policy apply to IVC filters in addition to other products?

A Yes. It applies to all the products we have across all of

11:07:36 the divisions within Bard.

Q Now, let's talk about Bard's practices in receiving and investigating complaints.

What are the various sources of where you receive the information that leads to complaints?

11:07:54 A We get it, certainly, directly from doctors. We get it

11:07:58 from sales reps from the company. We get -- we often review and read literature. So there's published studies that we look through and if we see our product mentioned, even though it may have limited information, we include that as a
11:08:13 complaint record. It may be -- I mean, those are the primary inputs. Customers themselves can call them in as well.

Q Does the company sometimes investigate reports of complications that you may see in the medical literature?

A Yeah. As I had mentioned, there's often new studies
11:08:40 published by doctors, institutions, and so when we see those things being published, it -- we log it first and then we have an obligation to conduct an investigation on it. Find out more information, find out what was the nature of the issue and get to the root cause, if possible, if there was alleged
11:09:03 failure.

Q Does the company maintain a 1-800 number that it publicizes to encourage physicians and others to report any complications or complaints?

A Yeah. It's included on instructions for use, packages,
11:09:19 boxes. So -- a website. So yes.

Q Now, over the years did the company maintain a group in Covington, Georgia, called MS&S? Explain to the jury what MS&S -- first of all, what does that acronym stand for?

A Medical service and support, if I remember correctly.

11:09:47 They're the people that answer most of the customer

11:09:50 service calls, so it's great. It could be everything from, hey, I can't find the instructions for use, can you give me a copy, or do you have a product that's this size, this shape, or if they have questions about the product itself, can you 11:10:06 use it in this circumstance. They field all of those questions.

But then they also field if there's any allegation of the device not performing the way they intended it, the way they want it to perform. They take that and transfer it to 11:10:20 the appropriate division complaint handling department. So they field all those and then shuttle them over to expertise -- people with expertise in dealing with complaints.

Q So if MS&S, that department, in Covington, Georgia, received a telephone call from a physician saying that some 11:10:42 IVC filter he had been implanting had perforated, for example, what would the MS&S department do with that report?

A They would note that in their records, but then they would transfer that call to the department here at the BPV to ask additional questions, to get more information to find out what 11:11:05 was the nature of the issue. You know, what, when, where, who. All the details we can.

Q What department at Bard is responsible -- for Bard Peripheral Vascular is responsible for receiving complaints?

A It's called field assurance. But complaint handling is 11:11:23 the same, but we called it field assurance.

11:11:26 Q And was field assurance under your jurisdiction as vice president of quality?

A Yes.

Q Now, do other employees in other departments have any role and responsibility in reporting complaints?

11:11:39 A Every employee in every department. In fact, every employee in every department in every division has responsibility, and we're trained on it. In fact, I've conducted training on it at company meetings.

11:11:58 Our responsibility is if you hear about an alleged issue, you need to turn around and send it -- send the information, get field assurance on the phone, give them that information right away because there's a time requirement. We've got to get to the bottom of what happened, what was the

11:12:17 allegation, what was the product involved very quickly.

Q Well, let's assume -- or in this scenario a sales representative for Bard Peripheral Vascular in Atlanta, for example, if that sales representative was at a hospital, saw a doctor and the doctor mentioned to him or her about some

11:12:38 incident involving an IVC filter, what would that sales representative's responsibility be in that circumstance?

A Within 24 hours they need to contact the field assurance group. They often follow up with maybe an e-mail. They leave voice mails for field assurance. We have some staggered hours

11:12:58 because we're in the west, so we have some early and late

11:13:03 people on the phone to take calls at off hours. They can call MS&S as well and have that fed through to DPV.

Q Does the field assurance department not only receive the complaints but also analyze and investigate them?

11:13:20 A They do. They first try to get as much information as they can, and then if they can get the device back, which isn't often, but we have a field assurance lab that has test methods, ways to test the device, measurement ability to make sure that it's conforming to the original specifications, and

11:13:45 other tests to evaluate it to see how it performed.

Q In your experience with IVC filters at Bard Peripheral Vascular, was there a pattern to when the complaints or issues might first be discovered by the doctor or patient?

A Related to IVC filters specifically?

11:14:03 Q Yes.

A It's really my understanding and that it's upon discovery -- there's really two times when they primarily report them. It's either during deployment, or placing the device originally, or when they go to retrieve the device. Or

11:14:23 if there's a symptom involved. So it's really those areas.

Q In your experience with IVC filters, were more of the complaints received by your department involving asymptomatic complications or symptomatic complications?

A I'd say symptomatic because they were -- they had a

11:14:54 symptom so they knew something was going on.

11:15:00 Symptomatic after the implant. So once it's placed then it would primarily be symptomatic.

Q Over the years, did the company receive as many complaints with the Simon Nitinol filter as it did with the retrievable

11:15:14 filters?

A Over the total of the years?

MR. O'CONNOR: Objection. Lack of foundation.

THE COURT: I think you need to lay foundation for that.

11:15:27 BY MR. NORTH:

Q Do you know generally about the number of complaints -- did you track and trend the number of complaints received regarding the Simon Nitinol filter in addition to the retrievable filters?

11:15:39 A Yes.

Q And do you have a general understanding of sort of the volume of complaints, comparatively speaking, between the permanent versus retrievable filters?

A Yes.

11:15:51 Q Based on that understanding and your tracking and trending of that data, did there appear to be more complaints involving the retrievable filters or the Simon Nitinol filter?

A Retrievable.

Q And as a part of your analysis as the vice president of

11:16:10 quality, did you identify any reasons why you thought that to

be the case?

A Because if they were asymptomatic, as in Simon Nitinol, you don't notice it. You kind of don't know that it's there. It's performing well, it's doing it's job. Compared to retrievable, if there's symptoms after deployment then -- then you have an event, you have a complaint event.

Q Was there anything you noticed as the vice president of quality and monitoring the tracking and trending with complication rates about the patient population with regard to Simon Nitinol filters that might impact the different complaint rates?

A Well, the Simon Nitinol being a permanent filter, I remember a study, I think one of the original studies of the Simon Nitinol, that they were placed in very sick patients. So -- ask the question again. Can you ask the question again, I --

Q Let's go on.

Let me ask you about this: Is it only the field assurance department that's involved with patients -- I'm sorry, involved in investigating complaints or do other departments of the company become involved sometimes?

A Yeah. I mean, we start with the field assurance group. They have quality engineers, trained and degreed engineers as part of the staff. Again, they get as much information as they can about the event. But then we get the R&D folks

11:17:50 involved, research and development. So the people who designed the devices that know the intent, the why behind the performance of the product. So we'll get them involved as subject experts on the device itself. So they were the ones
11:18:08 that originally helped design it and put the specifications together, so it's helpful to have them involved.

We may get manufacturing. For every complaint we also do a manufacturing interview. So we want to understand if there was something related to manufacturing that may have
11:18:27 caused the event. So there's a lot of people involved just beyond field assurance.

Q I think we've heard this testimony, but where were the IVC filters or are the IVC filters manufactured?

A In New York at one of our sites. Glens Falls. Glens
11:18:46 Falls.

Q And are there quality engineers and other people on-site at Glens Falls?

A Yes. Yes. There's manufacturing engineers, quality engineers, quality department structure, quality head who
11:19:02 reported to me as well.

Q Walk us through the process, if you will, when the company receives a complaint.

A We'll receive a description of an event from any number of multiple sources. And we may receive just a little bit of
11:19:23 information or may receive detailed information. What we do

11:19:27 is have someone follow up with the person who recorded that or reported that to us and we ask a series of questions.

In particular, for our IVC filters we'll ask when it was implanted? What's the patient's details? What are 11:19:44 physiological conditions? Name the hospital. Who's the reporting person? Name of the patient. And then the details of the device. Like I said, when was it implanted? How is it implanted? Because there's different ways to put it in. When did you first see an issue? When was the first experience of 11:20:10 something not being right? All those questions as part of the investigation. Then we'll say is the device explanted? Can we receive it back?

And if we should happen to get it back, we have that lab that we can do all sorts of analysis on it.

11:20:31 So we'll decontaminate it first and then take it to the lab, make sure we're measuring it, trying to analyze whether it's within specification or not.

We take that same information, record the lot number that the device was from, meaning each one of our devices is 11:20:54 made in a certain batch. We take that lot number, give it to manufacturing, and they look through all their records, is there anything related what's in the paperwork that was used to make the device related to what this allegation of the failure was.

11:21:08 And so we take all of that information together, we

11:21:11 prepare all that to the risk assessment. We get a -- and then when we have all that information, then we can code it. And we use FDA device codes, which are just alphanumeric numbers that really summarize what is the failure. If it's a device 11:21:35 breakage or device leak in other devices. If it's tearing of something. There's a numerical value that we can put multiple number of codes in, and that way it sort of summarizes the entire event so you can track and trend it easier rather than having to look through the narrative of every event we get.

11:21:54 Q Mr. Modra, does the field assurance people, folks that are investigating these complaints, do they attempt on occasion to talk to the physician involved in the procedure or with the device?

A Every time. We make at least three attempts to try to get 11:22:11 additional information from the physician, either through the hospital contact, through a sales rep, or through them directly. We try to get their experience because they're the ones that can give us their opinion on really what went on.

Q Does the company on occasion attempt to obtain medical 11:22:31 records?

A We ask for those as well because those are useful in -- they'll have the complete narrative of what happened during the event, leading right up to it, right afterward, and then how is the patient doing, what's the outcome of the device. 11:22:51 So, yeah, we have medical records; we ask for those as well.

11:22:55 Q Does Bard Peripheral Vascular have policies or procedures for when to report these complaints that have been investigated to the FDA?

A Yes. Per regulation we have a series of questions. A 11:23:12 questionnaire that gets filled out with every complaint and it helps walk the person through what would be reportable to the FDA and what isn't.

Q So if you determine a complaint is reportable to the FDA and you make that report, what's the term that the FDA uses 11:23:28 for that sort of complaint?

A Medical device reports. So MDR is the short -- short version.

MR. NORTH: If we could bring up Exhibit 5706, beginning at page 48.

11:23:42 BY MR. NORTH:

Q Mr. Modra, can you tell the members of the jury what you're looking at now, which is Exhibit 5706, beginning at page 48.

A It's the Standard for Medical Device Reporting CQA 11:24:02 standard 54.

Q And was this particular policy or standard in place, or a similar version of it, at the time you were vice president there?

A Yes.

11:24:19 Q And is this an official business record of Bard?

11:24:22 A Yes.
Q Is it kept in the course of the regularly -- regular business of the company?
A It is.
11:24:28 Q And was it a routine practice of the company to maintain such a policy?
A Yes.
Q In fact, was such a policy -- having such a policy required by the United States Food and Drug Administration?
11:24:39 A It is.
MR. NORTH: Your Honor, at this time we would tender Exhibit 5706, pages 48 to 61.
MR. O'CONNOR: One moment, I've got to talk to my lawyer.
11:24:54 No objection. Thank you.
THE COURT: Admitted.
(Exhibit 5706 admitted.)
BY MR. NORTH:
Q Does Bard investigate only complaints that are reported
11:25:09 from the United States?
Well, let me back up and ask this: Are Bard's products sold internationally?
A Yes.
Q Does Bard -- if Bard receives a complaint from overseas,
11:25:21 let's say Australia or Belgium, does your division investigate

those complaints also?

A Yes. If it's a product that's from Bard Peripheral Vascular, yes, we would be required to investigate that as well.

MR. NORTH: If we could look at --

First of all, could I display this, Your Honor? I'm sorry.

THE COURT: Yes.

BY MR. NORTH:

Q Does the policy for complaint reporting define the term "malfunction"?

A Yes.

Q And how is that defined?

A In 4.9. Malfunction.

Q And what's the point of having -- well, is "malfunction" sort of a term of art in the reporting to the FDA of various complaints?

A Yes.

Q And explain to us what that -- what the significance of that is.

A When you report an event to FDA, they ask you to report it in one of two ways, either malfunction or serious injury. So there's a definition for both of those.

MR. NORTH: And if we could look at 4.20.

BY MR. NORTH:

Q And is that the definition in your report for "serious injury"? I mean in your policy.

A That is.

Q And are these definitions made up by Bard Peripheral Vascular? Or where do they originate?

A No. They're intended to be consistent with the regulation. That's why they're in there.

Q Is there a clear-cut line between what constitutes a malfunction and what constitutes a serious injury, in your experience?

A There's -- in my experience, it's easy, obviously, to determine what a serious injury is. Those -- when injury's reported, that's very easily understood. Malfunction is a little less clear because there isn't a clear injury of -- alleged in the event.

Q How many Bard Peripheral employees are involved in investigating a single complaint when it arrives?

A At least three, but many more than that typically. There's quality engineers, there's field assurance oversight and management, quality assurance.

Q Well, let's talk about sort of a basic complaint where there would only be three people. Walk us through those steps, how three different people get involved in reviewing a single complaint.

11:28:44 A If person number 1 takes the event from the doctor, writes down that information, follows up on getting as much information as they can -- like I said, the date it was implanted, for instance, what were the circumstances leading 11:29:00 up to the experience, the event -- follows up with conducting the investigation themselves, like looking at the product if we get it back, writes up the summary, does the other analysis and steps, compares it to the risk assessments, and then they'll at least have another person where there's a field 11:29:21 assurance review that reviews did they document all that they should.

So they will review the records, and then a third person, that's why I said a minimum of three, is a quality assurance person, who's different from the other two folks, 11:29:35 will also look at the records to make sure that they're complete.

MR. NORTH: I'm sorry, I darkened the exhibit too quickly. Could we pull that back up and display it, Your Honor?

11:29:49 THE COURT: Yes.

MR. NORTH: If we could look at 5706, page 55.

And look at section 6.6.1.1.

BY MR. NORTH:

Q Mr. Modra, if Bard, in conducting this review, after three 11:30:19 people have looked at a complaint, are somehow in that

11:30:23 instance still unsure as to whether it qualifies for reporting to the FDA, what does the policy require?

A If there's some ambiguity, some things unknown with regard to whether or not it is MDR reportable, we report it.

11:30:44 Q Now, if Bard receives additional information after submitting the initial complaint to the FDA, what does the policy require Bard to do then?

A When you get additional information, which a lot of times you will, you'll request all that information up-front, like

11:31:01 maybe the medical records, and there's a requirement that within the first 30 days of receiving that event you have to make a decision of whether or not it's reportable. So you make that decision based on the information you have.

And then sometime later, if you get additional

11:31:17 information, maybe the doctor was busy or there was -- the information in the records weren't available, they may send that to you later. And if we get that, then we link that to an existing record that we filed.

We re-review the information and say before, was it

11:31:35 reported? How was it reported? And then does this new information change that requirement? And if it does, then we have to re-report it. So we send an addendum to FDA. There's a check box on the 3500A form that we check addendum to or update to the original MDR so it links them together.

11:31:58 Q Now, the tracking and trending that the company does, does

that generally determine the best evidence you have of various types of complication rates with devices?

A I would say so.

Q And I believe you told us you compute those on a regular basis with products?

A At least monthly, and we can run ad hoc whenever we want. But there's quite an extensive set of graphs, trends, summaries, analysis, that we present to management every month.

Q Now, the adverse event rates that you calculate, do you generally share those with physicians?

A No.

Q And why is that?

A You can't -- you can't just share information about that with physicians. It could be construed as you trying to sway them that maybe you have great rates and you're trying to convince them of the great performance of your device. You have to have clinically based evidence to share with doctors.

Q On occasion, has Bard reviewed data from the MAUDE database related to competitive filters on the market?

A Yeah. I mean, we review that data. We try to get as much information about competitors as we can. I mean, we'll look at literature, we'll review the FDA database, MAUDE, but then also if there's any information about the performance of their devices in other publications. Lot of times there's trade

11:33:40 shows and things. So we try to gather up all of that information to make assessments of the performance of the devices.

Q Is Bard able to actually determine a rate of complication for a competitor's filter from the MAUDE database alone?

11:33:54 A Not from MAUDE alone. I mean, it even has a disclaimer on there that you can't do that. But it's -- it's still subject to what did they report to the FDA. So, yeah, it's a bit of information, but you can't go solely on that.

11:34:22 Q Well, the MAUDE -- does the MAUDE database give you how many adverse events have been reported with a competitive filter?

A It does.

Q Does it give you, however, how many competitive filters of

11:34:39 that particular filter have been sold in the marketplace?

A No. It just gives account of the events of a certain type.

Q So if you wanted to get a denominator to determine a rate of a competitor's filter, where would you go? Or what sources

11:34:56 are there to try to find that?

A We might use IMS, which is a service -- I don't know what that acronym stands for -- but where we would get estimates of sales from competitors. But they're always time lag and there's some variability, I guess, in the business

11:35:19 intelligence of those. So we have that ability.

I guess you could try to find out their revenue of a certain product line and back calculate. But there's limited sources of getting truly accurate data from anyone else. I mean, intentionally so. It's competitors.

Q Well, does Bard try to compute competitive rates using that crude data at times?

A We do.

Q Based on your experience, do you ever share those estimates of competitive rates with physicians?

A No. Not in my experience.

Q Why is that?

A Well, it's sort of dirty pool, if you will. You don't want -- you don't -- you don't do that. I mean, you don't share someone else's rates. It's -- besides the fact you can't really do that accurately and it would not be allowed by FDA really to be publishing that sort of thing.

Q Based on your experience, why do you believe it would not be allowed by FDA?

A Just the advertising rules. When you have -- if you're advertising about your own product, you have to have a fair and balanced message. So even down to like the font size. So you can't say the product has this great performance and then put all of the warnings and all of that in micro font. I mean you have to have -- you can see them on TV. Fair and balanced communication of the risks and benefits of the device.

So similarly, in my experience, you'd have to have something like that. And we're not going to do that about a competitor's device.

Q Well, based on your experience with the FDA -- well, let me ask you this: Have you dealt with the FDA frequently in your role in quality assurance over the years?

A I would term it frequently, yes.

Q Based on your experience, do you believe that it would be permissible to publicize complication rates that were based on MAUDE data?

A No.

Q And why is that?

A One, because their disclaimer says that. Two, I wouldn't publish rates because of the potential inaccuracies. It would be pure speculation on our part on the denominator, so it wouldn't be appropriate to do that.

MR. NORTH: If we could look at Exhibit 7795.

BY MR. NORTH:

Q Could you identify what this is.

A Looks like the front page of the MAUDE database. You can search for a number of different things.

Q Are you familiar with that with your work with medical devices and the FDA?

A I am.

MR. NORTH: Your Honor, I believe this has already

been admitted. If we could display it to the jury?

THE COURT: You may.

MR. NORTH: And if you could look down at the second bullet point, please, Mr. Russell.

BY MR. NORTH:

Q Is that the disclaimer by the FDA you were mentioning earlier about the use of the MAUDE database to determine comparative rates?

A Yeah. That's what I would call the disclaimer.

MR. NORTH: You can take that down.

BY MR. NORTH:

Q Over the 20 years or so you have worked in the medical device industry, Mr. Modra, are you aware of any device manufacturer that has included its internal complication rates within its instructions for use?

A No. No. The only thing I've ever seen instructions for use are clinical study data, which is run by FDA before we can even put it in the instructions for use, and they require it of PMA products. High-risk products.

Q Are you familiar with what a DFMEA is?

A I am.

Q What is that?

A Device failure modes and effects and analysis document.

Q And are there certain rates calculated within a DFMEA?

A There are certain rates estimated within there for each

11:40:11 type of failure mode that a device is believed to have.
Q Over the 20 years or so you have worked in the medical device industry, are you aware of any device manufacturer that has included its estimated rates from a DFMEA in its
11:40:30 instructions for use? Or in other materials disseminated to physicians?
MR. O'CONNOR: Objection. Lack of foundation.
THE COURT: Overruled.
THE WITNESS: No. It would be inappropriate to
11:40:44 include some numbers from our internal tool for risk management. It wouldn't be appropriate. I've never seen it done.
MR. NORTH: If we could bring up Exhibit 5991.
BY MR. NORTH:
11:41:12 Q Do you recognize this document?
A Yes.
Q If could you tell us what this is.
A This is a FM or a form that's used to help guide through when you're given an event type. So when someone calls in an
11:41:32 event of an alleged failure of a device, that's along the left-hand side. And then it helps walk a person through whether that's automatically reportable as an MDR or whether there's some other things you have to ask or find out to determine if it's reportable, and then also how it's
11:41:52 reportable. Meaning as malfunction or serious injury. And

then also the related codes. So it helps tie together what the experience is and make the coding more consistent.

Q Is 5991, the guideline, is that specific to IVC filters themselves?

A Yes, that's the one for IVC filters. You can see it at the top.

Q And is this a record that was created and is kept as a regular course of Bard's business?

A It is.

Q And is it created by your department, your former department, under the supervision of the vice president of quality?

A It is.

Q And is it a routine practice of the company to make guidelines -- create guidelines such as this?

A Create and update. Yes.

MR. NORTH: Your Honor, at this time we tender Exhibit 5991.

MR. O'CONNOR: Your Honor, just a minor objection as to when was this first created.

THE COURT: Would you lay that foundation, please.

MR. NORTH: Yes, Your Honor.

BY MR. NORTH:

Q Do you know when this was created, Mr. Modra?

A This -- the first revision of this document?

Q Yes.
A Generally. I don't know the exact date.
Q Well, this was -- were these guidelines in place at the time that you worked there?
A Yes.
Q And this is revision, what, 5?
A That's correct.
Q And were you involved ever in revising these particular guidelines?
A I didn't actually make the redlines, but I was involved in the discussions about the details of those, so, yes.

MR. NORTH: Your Honor, if I could let the witness look at the entire 5991 to address any questions.

THE COURT: You may.

Is that marked?

MR. NORTH: It has 5991 on the bottom.

THE COURT: So that's part of the exhibit?

MR. NORTH: Yes.

THE COURT: Okay. Yes. Traci can give it to the witness.

MR. NORTH: Thank you.

MR. O'CONNOR: I'm sorry, is this the same one we have on the screen?

THE COURT: Yeah. It's the fuller document.

MR. O'CONNOR: Thank you.

11:44:34 BY MR. NORTH:

Q Look at the last page, if you would, Mr. Modra.

Does this indicate you yourself, as the VP of quality, approved this particular document?

11:44:50 A It does.

Q And this particular version of the guidelines?

A It does.

MR. NORTH: Your Honor, again we would tender the document at this time.

11:45:06 MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit 5991 admitted.)

BY MR. NORTH:

Q In developing the latest version of these guidelines, did

11:45:19 Bard work directly with the FDA to shape these guidelines?

A We did.

MR. NORTH: If we could turn -- first of all, if we could display this, Your Honor?

THE COURT: You may.

11:45:37 MR. NORTH: And if we could turn to page 9.

BY MR. NORTH:

Q If you would look down at the bottom, the final revision number, 5, and I believe -- did we establish earlier, Mr. Modra, this particular exhibit is revision 5 of this

11:46:04 document? Or guidelines?

11:46:06 A Yes, we did.
Q And where it says description for revision 5, what does it say?
A Revised based on outcome of Bard's meeting with FDA. And
11:46:19 references two technical documents.
Q Mr. Modra, is Bard's complaint analysis process and procedures highly regulated by the FDA?
A Yes.
Q Periodically, does the company do internal audits of its
11:46:45 own complaint handling systems?
A It does. It does through someone on-site who is designated as an internal auditor that operates independently from any of the rest of the quality department, and they report directly to me in that position. We also have Bard
11:47:04 corporate-level auditors that are independent from the division themselves. So they will come and review that field assurance department. And, also, we have outside auditors and we've had consultant experts come in and review specifically the field assurance department at least yearly. More
11:47:26 frequently lately.
Q And how often do -- does the company undertake these audits?
A At least once a year from each of those individuals. Field assurance is multiple times, more likely two. But at
11:47:44 least once a year.

11:47:47 Q What sort of outside entities do you call in to participate in the audit process on occasion?

A We have consultants, experts, that -- to give an independent view of, you know, maybe we're too close to the 11:48:02 process, maybe we don't see everything that they would see because they're unfamiliar with it.

So we call on and hire experts to come in and give us an audit, go through samples of records, talk to the people, make sure that they're following the procedure independently.

11:48:18 So it gives us an independent view of whether we're performing per the procedure and up to expectations.

Q Now, after the FDA clears a product for sale on the market, does the agency remain involved and conduct periodic audits of a manufacturer like Bard Peripheral?

11:48:45 A Yes.

Q What sort of audits does the FDA do?

A They do unannounced audits primarily. They will come in on a periodic basis, typically about every two years, come in and just show up at your door one day and then just ask to be 11:49:02 shown to the manufacturing floor, to a conference room where you're going to start pulling records, and they'll go through whatever they want to go through.

Q Did you say these audits sometimes occur unannounced?

A In my experience most of them are unannounced.

11:49:20 Q What's it like at Bard Peripheral when FDA shows up

11:49:25 unexpectedly one day?

A It is all hands on deck. So when you have -- when you get the notice that FDA has shown up to your front door, there is a call to me, there is -- I call all my directors, and then 11:49:38 there's a notification sent out that whatever they want, they get top priority. So pretty much all of the things you were doing, if you're involved as a subject matter expert or somebody who knows about a product that they're going to ask about, you need to be ready to go into a conference room and 11:49:57 answer their questions. So it's all hands on deck.

Q As part of an FDA audit, do they sometimes review the company's internal complaint files?

A In my experience, almost every time.

Q Do they review the company's procedures and policies like 11:50:18 the ones we've just shown, the guidelines and the MDR reportability and things of that nature?

A Yeah. The nature of their reviews are first they want to see the procedures, they want to see the guidelines, everything that you have that says how you're going to do this 11:50:34 process. And they familiarize themselves with that very quickly, and then they ask people questions about it. What do you do in this circumstances? What do you do after that? And then they want to see the records. Do your records match what you say you're doing and do they match what the procedure 11:50:50 tells you to do? And they go through a lot of records.

11:50:55 Q Does the FDA, as part of their audit process, review Bard -- the company's design methods?

A They do. It's called design controls under FDA regulation, but they want to understand -- back in the mid 11:51:09 '90s they had an emphasis on proper design controls because they determined a lot of the product issues were related to that. So they instituted these steps that you should follow for design control. So they're going to go back and want to see your design, it's called design history file. And it just 11:51:29 gives the entire history of the decisions you made, why you made those, what you tested, the extensive tests that you did, your risk management, how did you determine how risky the device was, and how you brought it to market.

Q As a part of the FDA audits, will they look at a company's 11:51:44 root cause analysis that might be done regarding any failure or complication mode?

A Right. It might be called CAPA, or corrective and preventive actions. But in a CAPA, root cause analysis is the end goal. You want to be able to prove that you can recreate 11:52:04 that failure and prevent that failure.

So we conduct those root cause analysis and they have a practice where in the past they've done CAPA plus one. So they always come in and look at CAPA, or root cause analysis, plus one other area. Typically field assurance or complaints. 11:52:23 Sometimes design, sometimes quality systems.

11:52:25 Q And approximately how often do these FDA surprise audits occur, in your experience?

A Typically two years is about the timing. So here at the facility in Tempe it's about every two years. Pretty routine.

11:52:43 Q Now, are these every-two-year audits unique to Bard Peripheral Vascular?

A No. No. The industry knows that every two to three years you're going to get an audit. And I've been to seminars with FDA where they've said, well if you -- certain criteria, they

11:53:07 can bump that up. And they can comp in any time they want. They can come in every six months if they want. So you just have to be ready, know that have you everyone available. That's why we have follow-ups on vacation and everything else.

Q Does the agency conduct these audits of all medical device

11:53:28 companies, to your knowledge?

A To my knowledge, yes.

Q And do they sometimes conduct them of manufacturing facilities of medical device companies?

A Yeah. Yes, they would. Not just the design center, but

11:53:37 the manufacturing locations for sure.

Q Do they sometimes conduct these audits of manufacturing facilities overseas for a medical device manufacturer?

A Yes. And in the last few years they've actually ramped that up as well. They've staffed up, is my understanding, and

11:53:54 spent a lot of time looking at suppliers, people that are

providing parts or components or materials to the U.S. as a point of emphasis.

Q Does the -- these audits every two years, do they sometimes result in FDA warning the company about possible deficiencies in policies, procedures, practices, things of that nature?

A They do. Obviously the goal is always not to have any nonconformances, but these days it's understood FDA uses that as a tool to communicate to the companies that these are the expectations, these are the new levels of expectations. So they're pretty frequent.

Q Does the FDA, when they find apparent deficiencies, do they issue what is called a warning letter?

A They do. They start with nonconformances and then they'll cite these deficiencies. And it's formally titled a warning letter.

Q And once a warning letter is issued, what is the process between the company that's received the warning letter and the FDA after that? What's the next step after receipt of a warning letter following an audit?

A Well, within 15 days you have to have complete answers to their questions. You have to respond to them and tell them what you're going to do. And it's not just -- in my experience, not just what they cited, but it's important for a company to communicate the full commitment of looking around

11:55:36 at the other processes. So if there's a specific item cited, you don't want to just say, oh, we fixed that. You want to look at that and is that an example of something similar that could have happened in another area. So you need to look around and then you need to put corrective actions in place to prevent those from occurring as well.

So it's very intensive immediately right after receiving that letter because within 15 days you have to have actions done and a plan that says how you're going to improve those other areas as well.

Q As a quality assurance professional in the industry for 20-plus years, are you generally familiar with FDA warning letters? Do you sort of monitor those?

A Yeah. One of the things that is important to keep on tab, tabs of, is others. Other companies' warning letters. So understanding what the FDA is saying and -- I mean, my personal understanding of why they may do that is they can send messages to companies industry-wide because everyone is watching those warning letters. So when they're published on the FDA website, there's services that will actually go out and publish them right to your doorstep the minute somebody else gets a warning letter, and it becomes public knowledge. They use that as the new standard.

So if FDA wants to communicate to us -- this is the way I look at it. If they want to tell us some way to do

that, they don't have to tell us. We're monitoring warning letters from other folks. So when we see that another company has received one, we often do a gap analysis. So we'll look at our processes versus what another company was cited in, and do we feel like we're doing it the same way? Do we feel like it we're doing it differently? And then we also do continuous improvement projects on those things as well.

Q In your experience, are FDA warning letters rare occurrences?

A Not really so much.

Q Before 2015, had FDA conducted audits of Bard's complaint handling systems at Bard Peripheral Vascular?

A Before 2015?

Q Right.

A Yes.

Q And can you -- was that approximately every two years, as you --

A Yes, it was.

Q And over the course of your time with the Bard Peripheral Vascular and your time at Bard Access, did you meet on occasion with FDA auditors?

A I did.

Q And prior to 2015, had there been an audit at Bard Peripheral Vascular that you had been involved with?

A There was.

Q How many before 2015?

A I believe there were two. I think 2011 and 2013.

Q And before 2015, had Bard BPV, Bard Peripheral Vascular ever received a warning letter, to your knowledge?

MR. O'CONNOR: Objection. Irrelevant.

THE COURT: Overruled.

THE WITNESS: No, not to my knowledge.

BY MR. NORTH:

Q Now, in the summer of 2015, did Bard receive a warning letter from the FDA?

A Yes. In July of 2015.

Q And you were the vice president of quality at that time?

A I was.

Q And was it your responsibility to investigate and respond to the FDA's warning letter?

A It was.

Q Want to focus on the warning letter with regard to complaint handling. Were you surprised when Bard Peripheral received that warning letter?

A Yes, because I really felt like we had responded pretty thoroughly to nonconformances cited, and we had undertaken systemic -- a lot of changes, a lot of improvements, really addressing what we thought were their expectations.

So, yes, I was surprised to get it because I thought we had really done all that they would have expected and more.

12:00:02 But in the end I know that it's a reality of the way that that is -- the process.

So on one hand surprised, but not entirely surprised.

Q Let me ask --

12:00:17 THE COURT: We're going to break at this point, Mr. North.

Ladies and gentlemen, we'll plan to resume at 1 o'clock. We will excuse you at this time.

(The jury exited the courtroom at 12:00.)

12:00:41 THE COURT: You can step down, Mr. Modra.

Please be seated.

Mr. North, how much longer do you think you have with Mr. Modra?

MR. NORTH: Your Honor, I think I've got at least an

12:00:51 hour more.

MS. REED ZAIC: Huh?

THE COURT: An hour.

MS. REED ZAIC: Thank you.

THE COURT: And he's your last witness?

12:01:01 MR. NORTH: Yes.

THE COURT: What is your best estimate, plaintiff's counsel, as to amount of time you'll use for rebuttal?

MR. O'CONNOR: I -- I don't think we have plans for rebuttal right now. But, honestly, with another hour of this

12:01:23 testimony, I'd have to see. But I don't think we have plans

12:01:28 for any rebuttal up to now.

THE COURT: No rebuttal evidence?

MR. O'CONNOR: Not at this point, Your Honor.

THE COURT: Okay. So when Mr. Modra finishes, at

12:01:40 present you're not planning on putting on any evidence; is that right?

MR. O'CONNOR: Mark O'Connor sitting here, no. But I don't think we are --

THE COURT: Well, last night --

12:01:48 MR. O'CONNOR: No, I agree --

THE COURT: I was told last night you were going to be calling --

MR. O'CONNOR: No, no, we don't have any plans. I just have to wait and see what's going to happen this next

12:01:55 hour.

THE COURT: I understand. I understand. Okay.

All right. Why don't we -- I want to get your comments on the jury instructions that I've handed out. Not now, but why don't we come back here at ten to 1:00 so I can

12:02:10 get your comments at that time.

And I will also do my best to give you my rulings on the two exhibits that we've talked about. I've got the case up that was cited by plaintiff this morning. I haven't read it, but I'll read it over the lunch hour.

12:02:25 And we can also talk about what -- about the issue we

talked about this morning before Dr. S. testified. That's a lot to do in ten minutes, but everybody needs to have a lunch break. So let's be back at ten to 1:00.

MR. O'CONNOR: Very good.

(Recess taken at 12:02.)

(End of transcript.)

* * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 28th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter